Key Legislation, Policies, and Agencies that got us here

- **US GoF Deliberative Process and Research Funding Pause -Nov 2014**

Planning Guidance for Recovery Following Biological Incidents DHS-May 2009

CRITICAL ANALYSIS OF BIOTERRORIST INCIDENTS,NATIONAL EXERCISES AND U.S. PREVENTION:USAF- April 2011

National Science Advisory Board for Biosecurity- 27 Nov 2012

World Bank: Financing Pandemics -Dec 2017

CEPI: Financing Pandemics-May 2017

The Apollo Program Bipartisan Commission *on* Biodefense- Jan 2021

A Global Deal for Our Pandemic Age: G20- Jan 2021

Outbreak Readiness & Business Impact Protecting Lives & Livelihoods across the Global Economy- Jan 2021

Financing the Global Commons for Pandemic Preparedness and Response: G20- Jan 2021

- **Memorandum of Understanding (MOU) 225-19-001**

The Athena Agenda: Bipartisan Commission on Biodefense- April 2022

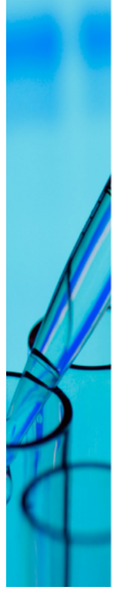
Key Legislation, Policies, and Agencies that got us here

- **Health Security & Bioterrorism Preparedness & Response Act of 2002**
- **Project Bioshield Act of 2004**
- **Public Readiness and Emergency Preparedness Act of 2005 (PREP)**
- **Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA)**
- **Pandemic and All-Hazards Preparedness Re authorization Act of 2013 (PAHPRA)**
- **21st Century Cures Act of 2016**
- **Public Law 115-92 FD&C Act of 2017**
- **FDA/DoD MOU Act of Nov 2, 2018**
- **Pandemic and All-Hazards Preparedness & Advancing Innovation Act of 2019**
- **Coronavirus Aid Relief and Economic Security Act (CURES Act of 2020**
- **National Blueprint for Biodefense Bipartisan Blue Ribbon Panel-Oct 2015**
- **S&T CBRN Defense Research Development Testing & Evaluation Strategy for 2021-2025**

- Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (2020)
- Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA)
- Public Law 115-92 (2017)
- 21st Century Cures Act (2016)
- Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA)
- Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA)
- Public Readiness and Emergency Preparedness Act of 2005 (PREP Act)
- Project BioShield Act of 2004
- Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)

- December 20, 2019: Department of the Army, the Surgeon General-Sponsored Assay Supports First-Ever FDA-Approved Ebola Vaccine in U.S. (DoD news release)
- December 19, 2019: FDA finalized the guidance Considerations for the Development of Dried Plasma Products Intended for Transfusion. This guidance provides recommendations for the development of safe and effective dried plasma products intended for transfusion; it finalizes the guidance of the same title dated October 2018.
- August 29, 2019: FDA Action Makes Blood Product More Accessible to Warfighters in Combat (DoD news release)
- November 2, 2018: Statement from FDA Commissioner Scott Gottlieb, M.D., on agency's approval of Dsuvia and the FDA's future consideration of new opioids
- October 29, 2018: FDA issues draft guidance on the development of dried plasma products intended for transfusion
- September 14, 2018: DoD and FDA collaborate to help speed potential countermeasures for Ebola and other viruses

OPERATION WARP SPEED



Tools for the Identification, Assessment, Management, and Responsible Communication of

Dual Use Research of Concern

A Companion Guide

to the United States Government Policies for Oversight of Life Sciences Dual Use Research of Concern

Prepared by the National Institutes of Health on behalf of the United States Government

SEPTEMBER 2014

National Health Security Strategy 2019-2022







EVENT 201

A GLOBAL PANDEMIC EXERCISE

A NATIONAL BLUEPRINT FOR BIODEFENSE:

LEADERSHIP AND MAJOR REFORM NEEDED TO OPTIMIZE EFFORTS

BIPARTISAN REPORT OF THE BLUE RIBBON STUDY PANEL ON BIODEFENSE

October 2015





Catastrophic Contagion

A GLOBAL CHALLENGE EXERCISE

U.S. Government Gain-of-Function Deliberative Process and Research Funding Pause on Selected Gain-of-Function Research Involving Influenza, MERS, and SARS Viruses

USAID | PREDICT



REDUCING PANDEMIC RISK, PROMOTING GLOBAL HEALTH

Ebola and Other Emerging Health Threats

Statement of
Robert Kadlec, MD, MTM&H, MS
Assistant Secretary For Preparedness and Response

ASPR
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

For Release on Delivery
Expected at
10am

S&T Chemical, Biological, Radiological, Nuclear Defense Research, Development, Testing & Evaluation Strategy 2021-2025

September 2021

Top 5 Takeaways for Using Other Transaction Authority (OTA)

The key take aways for understanding, developing, and utilizing OTA are listed below.

1. An OTA is a procurement authority that allows federal agencies to enter into agreements with non-traditional defense contractors, such as small businesses, research institutions, and nonprofit organizations.
2. They allows agencies to bypass certain Federal Acquisition Regulation (FAR) requirements, which can speed up the acquisition process and make it more flexible.
3. Can be used for a variety of purposes, including prototyping, research and development, and follow-on production.
4. Agreements are typically used for projects that are innovative, Medium to High-risk, or have a short timeline.
5. Agreements can be beneficial for both the government and contractors, as they can provide a faster and more flexible way to develop and acquire new technologies and capabilities. However, they may also be subject to greater scrutiny and oversight due to the unique nature of the agreements.



OBA Topics

- Biosafety
- Biosecurity
  - Dual Use Research of Concern
    - International Engagement
    - Dual Use Research: A Dialogue
  - National Science Advisory Board for Biosecurity (NSABB)
- Biomedical Technology Assessment

Home » Office of Biotechnology Activities » Biosecurity » Dual Use Research of Concern

Biosecurity

Dual Use Research of Concern

Dual Use Research of Concern (DURC) is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. The United States Government's oversight of DURC is aimed at preserving the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.

Watch the video "Dual Use Research: A Dialogue"

U.S. Government Policies, Materials and Activities

Gain-of-function deliberative process and funding pause

FAQs of gain-of-function deliberative process and funding pause

United States Government Policy for Institutional Oversight of Life Sciences Dual use Research of Concern (September 2014)

A. Qs & As on the U.S. Government Policies for Oversight of Life Sciences Dual Use Research of Concern

1. What are "dual use research" and "dual use research of concern (DURC)"?

Dual use research is research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that can be utilized for both benevolent and harmful purposes. Conceivably, much of life sciences research could be considered dual use—that is, most of the information it generates has some potential to be misused. Thus, both DURC policies focus on "dual use research of concern," or "DURC," which is defined as:

> *Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.*

Categories of research experiments that fall under DURC include those that do the following:

1. enhance the harmful consequences of the agent or toxin;
2. disrupt immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification;
3. confer to the agent or toxin resistance to clinically and/or agricultural useful preventative or treatment interventions against that agent or toxin or facilitates their ability to evade methods of detection;
4. increase the stability, transmissibility, or the ability to disseminate the agent or toxin;
5. alters the host range or tropism of the agent or toxin
6. enhance the susceptibility of a host population to the agent or toxin
7. generate or reconstitute an eradicated or extinct agent or one of the 15 DURC toxins or agents

What was the voluntary moratorium on laboratory research specific to the highly pathogenic A(H5N1) bird flu virus and what is the government's current stance on this research?

On January 20, 2012, a voluntary moratorium on laboratory research specific to the highly pathogenic A(H5N1) bird flu virus was announced in a letter signed by 39 international flu researchers. This moratorium, which was initially expected to last 60 days, was not lifted until January 23, 2013, due to the controversy surrounding the topic. This moratorium prompted the development of the U.S. Government's DURC policy , which was launched in March 2012. In October 2014, following publication of several controversial "gain of function" (GOF) studies as well as several high-profile incidents in U.S. biocontainment laboratories, the U.S. Government introduced another moratorium on all U.S. funded GOF research on certain "potential pandemic pathogens" (PPPs) , including influenza viruses, severe acute respiratory syndrome (SARS) and Middle East Respiratory Syndrome (MERS) viruses. On December 19, 2017, The U.S. Department of Health and Human Services (HHS) lifted this 3-year moratorium. The lifting of this moratorium allows certain types of U.S. government funded laboratory research studies involving these pathogens to resume. The types of studies that now can be conducted are governed by the HHS framework for guiding funding decisions about research involving enhanced potential pandemic pathogens, also known as the "HHS P3CO Framework," which also was released on December 19, 2017.

and their students at 6 leading institutes of public health, veterinary medicine, and environmental science in the USA.

East China Normal University, **Shanghai, China** (Shuyi Zhang and Guangjian Zhu)
Dr. Zhang is Dean of the Institutes for Advanced Interdisciplinary Research at East China Normal University. Over (b) (4) square metres is allocated to his research group at ECNU. The lab is fully capable of carrying out molecular, protein, epidemic disease and evolution research. Experimental equipment includes: Roche 454 (GS FLX Titanium System), Bioinformatics Computer Server, Multi-Channel Neurophysiology Workstation TDT, PCR Amplifier, Real time PCR Amplifier, Electrophoresis, Ultra-low Temperature Freezer, Centrifuge, UV-Visible Spectrophotometer, Two-dimensional Electrophoresis, Vertical Electrophoresis System, Incubator, Clean Bench, and Class II-Biosafety Cabinet, Hybridization Oven, Water PurificationSystem, and Shaker.

Wuhan Institute of Virology, Wuhan, China (Zhengli Shi and Xingyi Ge)
The Shi laboratory includes 4 rooms totaling (b) (4), one equipped with two CO2 incubators for tissue culture, one equipped facilities including with high speed centrifuge, 2 -20°C, 3 -80°C freezers, 2 PCR machines, 1 ELISA plate reader, one for molecule diagnosis equipped with two biosafety cabinets, and one normal laboratory equipped

Implementation of the *USG Policy for Institutional Oversight of Life Sciences DURC*: Illustrative Case Studies

The purpose of the *USG Policy for Institutional Oversight of Life Sciences DURC* is to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, and technologies provided by such research. The Policy requires research institutions to establish a process for identifying dual use research of concern (DURC) and to implement risk mitigation measures for conducting and communicating such research. In the first step in this process, the principal investigator (PI) identifies research involving one or more of the 15 agents or toxins listed in the policy, and assesses whether the research can be reasonably anticipated to produce any of the seven listed experimental effects. The PI then refers the relevant research, including his/her assessment, to an Institutional Review Entity (IRE). The IRE reviews the PI's assessment and determines whether indeed the research involves any of the seven experimental effects, and if so, the IRE determines whether the research meets the definition of DURC, as defined in the policy. The IRE then works with the PI and the USG funding agency to develop a risk mitigation plan for responsibly conducting and communicating the DURC.

NIAID PROVIDER TO FOR-PROFIT | NIAID TRACKING NUMBER: **2017-1210**

MATERIAL TRANSFER AGREEMENT

This Material Transfer Agreement ("MTA") has been adopted for use by the National Institute of Allergy and Infectious Diseases ("NIAID"), an institute at the National Institutes of Health, which is part of the Department of Health and Human Services, an agency of the United States Government ("Provider") in transfers of research material to for-profit institutions for internal research.

Recipient: **ModernaTX, Inc.**, having offices at 500 Technology Square Cambridge, MA 02139, created and operating under the laws of Delaware.

1. Provider agrees to transfer to Recipient's Investigator the following material(s), including known functional components or subunits and unmodified descendants thereof ("Research Material"):

Name/Description	Reference
Cell line #1: RajiDCSIGN	PMID: 16415006 and PMID: 18005691
Cell line #2: RajiDCSIGNR	PMID: 16415006 and PMID: 18005691

2. THIS RESEARCH MATERIAL MAY NOT BE USED IN HUMAN SUBJECTS. The Research Material will only be used for commercial research purposes by Recipient's Investigator in his/her laboratory, for the research project described below, under suitable containment conditions. **The Research Material will not be used in any product offered for sale or processes for the manufacture thereof, including quality control procedures, or in commercial services for which a commercialization license from the National Institutes of Health ("NIH") is required. The Research Material and methods of using the Research Material are the subject of U.S. and foreign patent applications. Please contact the TTIPO, NIAID, if information is desired concerning the present status of this invention or how to license the Research Material and/or patents covering the Research Material.**

Recipient agrees to comply with all laws, rules and regulations applicable to the Research Project and the handling of the Research Material.

a. Is the Research Material of human origin?

☐ Yes ☒ No

b. If Yes in 2a, was Research Material collected according to 45 C.F.R. Part 46, "Protection of Human Subjects"?

☐ Yes Please provide Assurance Number: _____
☐ No

3. This Research Material will be used by Recipient's Investigator solely in connection with the following research project ("Research Project") described with specificity as follows:

The Recipient will use the Research Material to perform neutralizing titer assays Proprietary Info Proprieta as an immunogenicity readout for several *in vivo* studies the Recipient will run in support of its vaccine programs Proprietary Info

PUBLIC HEALTH SERVICE

MATERIAL TRANSFER AGREEMENT

This Material Transfer Agreement ("MTA") has been adopted for use by the National Institutes of Health, the Food and Drug Administration and the Centers for Disease Control and Prevention, collectively referred to herein as the Public Health Service ("PHS") in all transfers of research material (Research Material) whether PHS is identified below as its Provider or Recipient.

Providers: *National Institute of Allergy and Infectious Diseases, National Institutes of Health ("NIAID")*
ModernaTX, Inc ("Moderna")

Recipient: The University of North Carolina at Chapel Hill

1. Provider agrees to transfer to Recipient's Investigator the following Research Material:

mRNA coronavirus vaccine candidates developed and jointly-owned by NIAID and Moderna.

2. THIS RESEARCH MATERIAL MAY NOT BE USED IN HUMAN SUBJECTS. The Research Material will only be used for research purposes by Recipient's Investigator in his/her laboratory, for the research project described below, under suitable containment conditions. This Research Material will not be used for commercial purposes such as screening, production or sale, for which a commercialization license may be required. Recipient agrees to comply with all Federal rules and regulations applicable to the Research Project and the handling of the Research Material.

a. Are the Research Materials of human origin?

___ Yes X No

b. If Yes in 2a, were Research Materials collected according to 45 CFR Part 46, "Protection of Human Subjects"?

___Yes Please provide Assurance Number: _____
___No

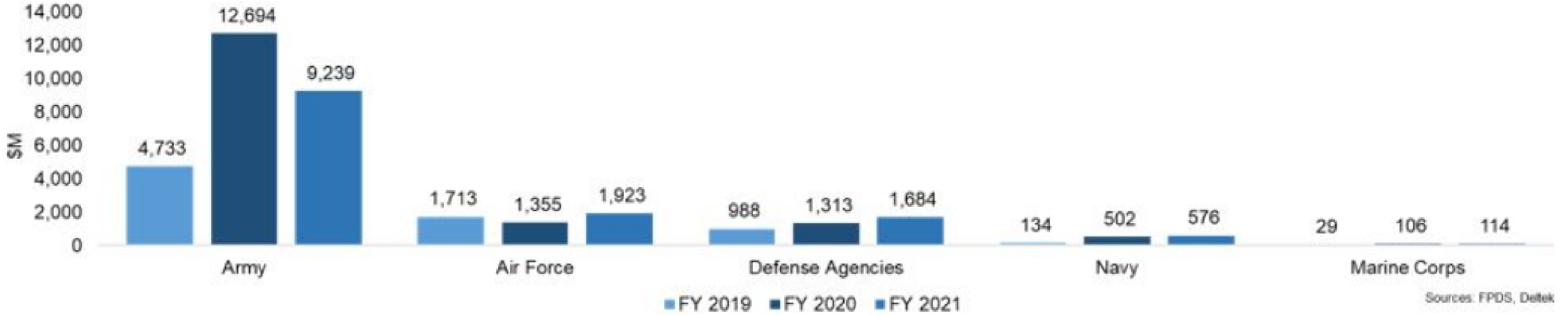
3. This Research Material will be used by Recipient's Investigator solely in connection with the following research project ("Research Project") described with specificity as follows (use an attachment page if necessary):

Perform challenge studies with the mRNA vaccine in a Proprietary Info model as described on Exhibit A.

4. Upon a Provider's reasonable request, Recipient will furnish a status report to such Provider regarding the use of the Research Materials and any data or results generated therefore. In all oral presentations or written publications concerning the Research Project, Recipient will acknowledge Providers' contribution of this Research Material unless requested otherwise. To the extent permitted by law, Recipient agrees to treat in confidence, and not to disclose to third parties or use for any purpose other than the performance of the Research Project, for a period of three (3) years from the date of its disclosure, any of Providers' written information about this Research Material that is stamped "CONFIDENTIAL," except for information that was previously known to Recipient or that is or becomes publicly available or which is disclosed to Recipient without a confidentiality obligation. Any oral disclosures from Providers to Recipient shall be identified as being CONFIDENTIAL by notice delivered to Recipient within ten (10) days after the date of the oral disclosure. Notwithstanding the foregoing, all information disclosed by Providers relating to Proprietary Info Proprietary Info of the Research Material will be treated as CONFIDENTIAL information as set forth above, whether or not marked or otherwise identified as "confidential." Recipient may publish or otherwise

Total DOD OTA Spending by Organization

When it comes to OTA-related spending, the Army stands head and shoulders above the rest of the DOD. This is true regardless if the good or service being purchased is IT-related or not.



The Army outspends all of the rest of DOD on OTAs by a lot every year. The discrepancy reached a high point in FY 2020 when the Army spent nearly four-times as much on its OTA projects than all of the other DOD organizations combined. This ratio of Army to DOD OTA spending decreased to just over two-times in FY 2021 as the Army reduced its spending while other parts of the DOD slightly increased theirs.

The bottom line is that if a company wants to maximize its earning potential doing OTA-related work it really needs to be laser-focused on working with the Army, and then the Air Force, before any other part of the department.

Federal Contracting

Federal agencies are using other transaction agreements to respond to the pandemic, which are contracting mechanisms that can enable agencies to negotiate terms and conditions specific to a project. GAO found that HHS misreports its other transaction agreements related to COVID-19 as procurement contracts, including other transaction agreements with about $1.5 billion obligated for Operation Warp Speed and other medical countermeasures. HHS's approach is inconsistent with federal acquisition regulations and limits the public's insight into the agency's contract spending. **To ensure consistent tracking and transparency of federal contracting activity related to the pandemic, GAO recommends that HHS accurately report data in the federal procurement database system and provide information that would allow the public to distinguish between spending on other transaction agreements and procurement contracts.**HHS concurred with this recommendation.

December 2, 2020

(b) (6)
Merck Sharp & Dohme Corp.
2000 Galloping Hill Rd.
Kenilworth, NJ 07033

Re: Letter Agreement to Rapidly Develop Manufacturing and Distribution Capability of CD24Fc for the Treatment of Severe and Critical COVID-19

Dear (b) (6)

Pursuant to 10 U.S.C. § 2371b, the U.S. Government is issuing this letter agreement to Merck Sharp & Dohme Corp. ("Merck") through Army Contracting Command on behalf of the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense and the Biomedical Advanced Research and Development Authority. This letter agreement is effective upon execution by both parties and will remain in effect until delivery of the product required under this letter agreement, replacement by a definitive agreement, or earlier termination by either party as described below.

In response to the worldwide COVID-19 pandemic and Public Health Emergency caused by the novel coronavirus SARS-CoV-2, the U.S. Government has identified CD24Fc, as a first-in-class biologic for treatment of severely and critically ill COVID-19 patients. The CD24Fc product has progressed rapidly through advanced research and development activities without U.S. Government funding. Merck, upon completion of its acquisition to acquire CD24Fc, is proposing to manufacture at-scale and fill and finish the therapeutic CD24Fc for treatment of the SARS-CoV-2 threat, for provision to the U.S. Government, subject to technical, clinical and regulatory success if clinical trials are successful and the FDA grants an Emergency Use Authorization ("EUA"). This letter agreement is necessary to meet certain development and manufacturing deadlines, as described below, including the need to reserve manufacturing suite space. The parties expect to enter into a definitized agreement no later than 180 days from the date of this letter agreement that more fully sets forth the terms and conditions of this agreement.

The desired end product of this effort is: submission of an EUA request no later than March 31, 2021, with FDA approval of the EUA request no later than June 30, 2021; the development of a proven at-scale manufacturing process capable of producing 100,000 doses by June 30, 2021; and development of a distribution process capable of delivering CD24Fc to point of care facilities (hereinafter referred to as the "Prototype Project" or "Technology"). The parties understand there are manufacturing uncertainties and, therefore, Merck shall use commercially reasonable efforts to successfully perform the Prototype Project pursuant to the statement of work included as Attachment A. In return, the USG shall pay Merck $355,562,292

PUBLIC HEALTH SERVICE

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

This Agreement is based on the model Cooperative Research and Development Agreement ("CRADA") adopted by the U.S. Public Health Service ("PHS") Technology Transfer Policy Board for use by components of the National Institutes of Health ("NIH"), the Centers for Disease Control and Prevention ("CDC"), and the Food and Drug Administration ("FDA"), which are agencies of the PHS within the Department of Health and Human Services ("HHS").

This Cover Page identifies the Parties to this CRADA:

The U.S. Department of Health and Human Services, as represented by

National Institute of Allergy and Infectious Diseases ("NIAID")

an Institute or Center (hereinafter referred to as the "**IC**") of the

NIH

and

Moderna Therapeutics, Inc.
hereinafter referred to as the "**Collaborator**",
having offices at 320 Bent Street, Cambridge, MA 02141,
created and operating under the laws of the State of Delaware.

COVID-19 VACCINE CONTRACT ACCOUNTABILITY

How Operation Warp Speed's Big Vaccine Contracts Could Stay Secret

September 29, 2020 · 3:40 PM ET

Heard on All Things Considered

By Sydney Lupkin

COVID-19 VACCINE CONTRACT ACCOUNTABILITY

How Operation Warp Speed's Big Vaccine Contracts Could Stay Secret

The Trump administration has compared Operation Warp Speed's crash program to develop a COVID-19 vaccine to the Manhattan Project. And like the notoriously secretive government project to make the first atomic bomb, the details of Operation Warp Speed's work may take a long time to unravel.

One reason is that Operation Warp Speed is issuing billions of dollars' worth of coronavirus vaccine contracts to companies through a nongovernment intermediary, bypassing the regulatory oversight and transparency of traditional federal contracting mechanisms, NPR has learned.

Instead of entering into contracts directly with vaccine makers, more than $6 billion in Operation Warp Speed funding has been routed through a defense contract management firm called Advanced Technologies International, Inc. ATI then awarded contracts to companies working on COVID-19 vaccines.

COVID-19 VACCINE CONTRACT ACCOUNTABILITY

How Operation Warp Speed's Big Vaccine Contracts Could Stay Secret

As a result, the contracts between the pharmaceutical companies and ATI may not be available through public records requests, and additional documents are exempt from public disclosure for five years.

Vaccine contracts awarded this way include $1.6 billion for Novavax, $1.95 billion for Pfizer, $1.79 billion for Sanofi and $1 billion for Johnson & Johnson.

> Many were OTAs that weakened or excluded Bayh-Dole clauses, which, among other things, allow the government to "march in" and take control of a drug or vaccine if a manufacturer that received federal funding engages in price gouging, for example.

Implementation of the U.S. Government Policy for Institutional Oversight of Life Sciences DURC: Case Studies

Prepared by the National Institutes of Health
on behalf of the United States Government

September
2014

- **Memorandum of Understanding (MOU) 225-19-001**
- **National Blueprint for Biodefense Bipartisan Blue Ribbon Panel-Oct 2015**
- **S&T CBRN Defense Research Development Testing & Evaluation Strategy for 2021-2025**
- **US GoF Deliberative Process and Research Funding Pause -Nov 2014**



What is "gain-of-function" research?

"Gain of function" refers to any modification of a biological agent that confers new or enhanced activity. Typically, researchers mutate or alter genes and examine the impact of these modifications on a particular property or trait of the organism. For example, some investigators can modify influenza viruses in ways that enhance pathogenicity and/or transmissibility in order to better understand the origins and nature of these traits at the molecular level, as well as their pathogenesis in susceptible hosts. Since influenza viruses constantly evolve in nature, these gain-of-function studies may help predict whether these viruses could evolve naturally over time to acquire these new or enhanced traits, and if so, how the viruses might affect hosts and the kinds of medical countermeasures that might be most effective. Some gain-of-function studies may entail biosafety and biosecurity risks that require unique risk assessment and mitigation measures.

Why is the U.S. government1 pausing the funding of certain types of gain-of-function studies at this time?

The occurrence this year of laboratory biosafety incidents at U.S. government research facilities have caused the federal government to re-assess the risk/benefit calculus underpinning funding decisions for a certain subset of gain-of-function research involving agents that pose a significant risk to public and animal health. The pause will allow the U.S. government, in partnership with the life sciences community, to conduct a comprehensive assessment of gain-of-function research with the explicit goal of developing a new policy framework to guide future funding decisions.

What is the scope of research covered by the funding pause?

During the pause, the U.S. government will not release new funding for gain-of-function research projects that reasonably may be anticipated to confer attributes to influenza[2], Middle East Respiratory Syndrome (MERS), or Severe Acute Respiratory Syndrome (SARS) viruses such that the resulting virus has enhanced pathogenicity and/or transmissibility (via the respiratory route) in mammals. This means that the U.S. government will not release new funding for experiments that meet the gain-of-function funding pause criteria. For the small subset of ongoing work that is determined to meet the gain-of-function funding pause criteria, the contract-funded work has been stopped and the grant-funded work is subject to a voluntary pause. The funding pause will not apply to characterization or testing of naturally occurring influenza, MERS, and SARS viruses, unless these tests reasonably are anticipated to increase transmissibility or pathogenicity.



Are experiments involving isolated genes of influenza, MERS, or SARS virus included in the funding pause?

No. The pause applies to research that would create viruses with certain attributes. If the research does not include production of infectious, replication-competent virus, then it would not be subject to the pause.

Is there a provision to allow gain-of-function research subject to the funding pause to proceed, for example, if the research is required for public health or national security purposes?

Yes, an exception from the funding pause may be granted by the head of the federal funding department or agency if that official determines in writing that the research is urgently necessary to protect public health or national security.

July 2, 2012
PHE Security Advisory Panel

Public Health Emergency
Public Health and Medical Emergency Support for a Nation Prepared

PHE Home > Preparedness > Legal Authorities > Boards and Committees > Federal Experts Security Advisory Panel

Federal Experts Security Advisory Panel

The Federal Experts Security Advisory Panel (FESAP) was established by Executive Order 13546 on July 2, 2010 to provide recommendations related to the security of biological select agents and toxins (BSAT) to the Secretaries of Health and Human Services and Agriculture and the Attorney General. BSAT are defined in the Select Agent Regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331).

The information provided on this page, including reports and recommendations, reflects the consensus views of the FESAP membership and not necessarily the views of their respective Departments, Agencies, and Offices, including the Select Agent Program. Any recommendations requiring regulatory change, if accepted by the Select Agent Program, will be published in the Federal Register as part of the rulemaking process. The anticipated posting date is October 2011. The public will have an opportunity to comment on the proposed rules at that time.

For further questions or comments on the activities of the FESAP, please contact Dr. Laura Kwinn, Executive Secretary, via the Federal Experts Security Advisory Panel Contact Form. Any comments or questions provided through this link will be used for the future work of the FESAP.

July 2, 2012
EO 13546

Federal Register
Vol. 75, No. 130
Thursday, July 8, 2010

Presidential Documents

Title 3—

The President

Executive Order 13546 of July 2, 2010

Optimizing the Security of Biological Select Agents and Toxins in the United States

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Policy.* It is the policy of the United States that:

(a) A robust and productive scientific enterprise that utilizes biological select agents and toxins (BSAT) is essential to national security;

(b) BSAT shall be secured in a manner appropriate to their risk of misuse, theft, loss, and accidental release; and

(c) Security measures shall be taken in a coordinated manner that balances their efficacy with the need to minimize the adverse impact on the legitimate use of BSAT.

Sec. 2. *Definitions.* (a) "Select Agent Program" (SAP) means the regulatory oversight and administrative activities conducted by the Secretaries of Health and Human Services and Agriculture and the Attorney General to implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Agricultural Bioterrorism Protection Act of 2002.

(b) "Select Agent Regulations" (SAR) means the Federal regulations found in Part 73 of Title 42 of the Code of Federal Regulations, Part 331 of Title 7 of the Code of Federal Regulations, and Part 121 of Title 9 of the Code of Federal Regulations.

(c) "Biological Select Agents and Toxins" means biological agents and toxins with the potential to pose a severe threat to public health and safety,

FDA and DoD formalize collaboration to advance medical products in support of American military personnel

New Memorandum of Understanding aligns agency efforts to foster the development and use of safe and effective medical products for members of the U.S. military

For Immediate Release: December 02, 2018

Dec 02, 2018

Today, the U.S. Food and Drug Administration and the Department of Defense's (DoD) Office of Health Affairs signed a Memorandum of Understanding regarding medical product development and assessment. This builds upon the work of both agencies to foster and prioritize the efficient development of safe and effective medical products intended to save the lives of American service members.

"We're extremely grateful to the men and women who defend our nation, often at great personal risk and sacrifice. It's our honor and duty to support our military personnel by ensuring they have access to safe and effective medical products – especially products that meet the unique needs and settings in which soldiers may require medical treatment," said FDA Commissioner Scott Gottlieb, M.D. "The FDA has already been working closely with the DoD to identify opportunities to expedite availability of medical products, particularly those products used to treat injuries in battlefield settings. For example, as noted below, the Emergency Use Authorization for French freeze-dried plasma that was issued earlier this year. Our close collaboration with DoD has helped us target and more efficiently address DoD's immediate product priorities and foster development and review of these products in the most streamlined manner possible. We are looking forward to additional partnership opportunities under the MOU."

MOU 225-19-001

Memorandum of Understanding Concerning Coordination With The Food and Drug Administration Regarding Department of Defense Medical Product Development and Assessment

Preamble

On December 12, 2017, the President signed into law Public Law No. 115-92 (P.L. 115-92), an Act to amend the Federal Food, Drug, and Cosmetic Act (FD&C Act) to authorize additional emergency uses for medical products to reduce deaths and severity of injuries caused by biological, chemical, radiological or nuclear (CBRN) agents or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to the U.S. military forces and for other purposes. P.L. 115-92 requires enhanced collaborations and communication between the U.S. Department of Defense (DoD) and the U.S. Food and Drug Administration (FDA) on DoD's medical product priorities (MPPs) for military emergencies. This Memorandum of Understanding (MOU) implements the framework for this Congressionally-directed collaboration between DoD and FDA (collectively, "the Parties").

I. Purpose

To implement P.L. 115-92 through an efficient collaboration between DoD and FDA in

Content current as of:

03/02/2020

Dec 02, 2018

The MOU formally establishes the framework under which the DoD and the FDA will implement the law passed by Congress in 2017 for enhanced engagements between the DoD and the FDA. Under the terms of this MOU, the FDA will work closely with the DoD to evaluate how best to foster access to safe and effective medical products that serve the military's medical needs; give the highest level of attention to and expedite review of priority DoD medical products; provide ongoing technical advice to aid in the rapid development and manufacturing of medical products for use by the military; and examine products currently under development to determine opportunities to streamline review and expedite their availability. The 2017 law also expanded the FDA's authority to authorize emergency uses of medical products to reduce deaths and severity of injuries caused by chemical, biological, radiological or nuclear (CBRN) agents or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to the U.S. military forces and for other purposes.

As part of the ongoing and frequent collaborations between the FDA and the DoD, additional steps taken over the past several months include:

- In July 2018, the FDA granted an Emergency Use Authorization (EUA) for the DoD's emergency use of Pathogen-Reduced Leukocyte-Depleted Freeze-Dried Plasma manufactured by the Centre de Transfusion Sanguine des Armées (often referred to as French freeze-dried Plasma). That action reflected the importance that both the DoD and the FDA place on efficiently prioritizing and expediting availability of potentially life-saving biological products that are essential to the urgent care of military personnel, especially those in potential battlefield settings. Granting this authorization supported access to this important product and ensures that it will be available if needed.
- In July 2018, the FDA approved the atropine autoinjector device as a medical countermeasure for chemical nerve agent exposure. This drug-device product was developed in partnership with the Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense, and was approved six months ahead of the DoD's product development schedule.

Jan 2017-Nov 2018

Enhanced Engagements for Products Relevant to the Department of Defense (DoD)

Public Law 115-92, enacted December 12, 2017, authorized the Department of Defense (DoD) to request, and the U.S. Food and Drug Administration (FDA) to provide, assistanc to expedite development and the FDA's review of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. On January 16, 2018, the FDA and DoD announced the launch of a joint program to prioritize the efficient development of safe and effective medical products intended for deployed American military personnel.

Public Law 115-92 (H.R.4374)

Amendment to authorize additional emergency uses for medical products to reduce deaths and severity of injuries caused by agents of war, and for other purposes

Public Law 115-92, enacted December 12, 2017, amended section 564 of the FD&C Act to allow for emergency uses of medical products for threats in addition to biological, chemical, radiological, or nuclear agent(s), to include other agents that may cause or are associated with, an imminently life-threatening and specific risk to the U.S. military forces. Public Law 115-92 also authorized the Department of Defense (DoD) to request, and FDA to provide, assistance to expedite development and the FDA's review of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel.

On January 16, 2018, FDA and DoD announced the launch of a joint program to prioritize the efficient development of safe and effective medical products intended for deployed American military personnel.

On November 2, 2018, FDA and DoD announced the signing of a Memorandum of Understanding (MOU), to provide the framework under which FDA and DoD will implement the law.

H.R.4374 - To amend the Federal Food, Drug, and Cosmetic Act to authorize additional emergency uses for medical products to reduce deaths and severity of injuries caused by agents of war, and for other purposes.

115th Congress (2017-2018)

LAW Hide Overview ×

Sponsor: Rep. Walden, Greg [R-OR-2] (Introduced 11/13/2017)

Committees: House - Energy and Commerce; Armed Services

Latest Action: 12/12/2017 Became Public Law No: 115-92. (All Actions)

Tracker: Introduced > Passed House > Passed Senate > To President > Became Law

More on This Bill
Constitutional Authority Statements
CBO Cost Estimates [0]

Subject — Policy Area:
Health
View subjects »

Public Law (PL) 115-92

What is Public Law (PL) 115-92?

On December 12, 2017, the President signed into law Public Law No. 115-92 (P.L. 115-92), an Act to amend the Federal Food, Drug, and Cosmetic Act (FD&C Act) to authorize additional emergency uses for medical products to reduce deaths and severity of injuries caused by chemical, biological, radiological, or nuclear (CBRN) agents or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to the U.S. military forces and for other purposes. P.L. 115-92 requires enhanced collaborations and communication between the U.S. Department of Defense (DoD) and the U.S. Food and Drug Administration (FDA) on DoD's medical product priorities (MPPs) for military emergencies.

What are the features of PL 115-92?

P.L. 115-92 amended the FD&C Act to provide, among other things, specific policy for increased DoD-FDA collaboration on the development and availability of MPPs. In summary, P.L. 115-92:

- Expands FDA's emergency use authorization (EUA) authority under §564 of the FD&C Act to allow FDA to issue EUAs for emergency use of unapproved medical products or unapproved uses of approved medical products to address additional types of threats (beyond CBRN agents) related to attack with an "agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to the United States military forces" (see §1(a), P.L. 115-92);
- Allows the Secretary of Defense to request, and authorizes FDA to take, specific actions to expedite the development of medical products, and the review of investigational submissions, applications for approval/licensure, and submissions/notifications for clearance for such medical products reasonably likely to diagnose, prevent, treat, or mitigate a specific and life-threatening risk to the U.S. military (see §1(b), P.L. 115-92); and
- Requires semi-annual review between DoD and FDA on DoD's MPP portfolio and requires quarterly DoD-CBER meetings for CBER-regulated MPPs (see §1(b)(3), P.L. 115-92).

How will PL 115-92 be implemented?

USAMRDC and the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) have been working with the office of the Deputy Assistant Secretary of Defense for Health Readiness Policy and Oversight (DASD(HRP&O)) to implement P.L. 115-92. The main features of this implementation are:

- A Memorandum of Understanding (MOU) between DoD and FDA to implement the new collaboration was signed on November 2, 2018. This MOU was negotiated by the Commissioner of Food and Drugs and the Principal Deputy Assistant Secretary of Defense for Health Affairs (PDASD(HA)) with the assistance of our legal and regulatory teams.
- The Medical Product Acceleration Committee (MPAC) has been informally established to manage the creation and maintenance of the DoD Priority List of MPPs that will be communicated to FDA, via the Assistant Secretary of Defense for Health Affairs (ASD(HA)), at the Semi-Annual and CBER Quarterly meetings required by the statute. The MPAC is intended to serve as the DoD enterprise-wide forum for discussions on which products are identified as DoD MPPs for the Priority List. The MPAC aims to achieve a DoD "one voice" approach envisioned by the statute.

What will be the impact on DoD Medical Product Development?

P.L. 115-92 has already significantly benefited DoD medical product development. The recent EUA for French Freeze Dried Plasma, the FDA approval of tafenoquine for the prevention of severe malaria, and the approval the atropine autoinjector for the treatment of chemical nerve agent poisoning, among other examples, are all fruits of this new collaboration. We expect this statute to expedite review and approval of DoD medical products and enhance DoD-FDA collaboration. Future success will depend on (i) the level of coordination and communication horizontally across the DoD enterprise, and (ii) the clarity with which DoD speaks with "one voice" to FDA.

§ 73.3 HHS select agents and toxins.

(a) Except for exclusions under paragraphs (d) and (e) of this section, the HHS Secretary has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to public health and safety. The select agents and toxins marked with an asterisk (*) are designated as Tier 1 select agents and toxins and are subject to additional requirements as listed in this part.

(b) HHS select agents and toxins:

Abrin
Bacillus cereus Biovar *anthracis**
Botulinum neurotoxins*
Botulinum neurotoxin producing species of *Clostridium**
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)[1]
Coxiella burnetii
Crimean-Congo hemorrhagic fever virus
Diacetoxyscirpenol
Eastern equine encephalitis virus
Ebola virus*
*Francisella tularensis**
Lassa fever virus
Lujo virus
Marburg virus*
Monkeypox virus
Far Eastern subtype
Siberian subtype
Kyasanur Forest disease virus
Omsk haemorrhagic fever virus
Variola major virus (Smallpox virus)*
Variola minor virus (Alastrim)*
*Yersinia pestis**
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 influenza virus)
Ricin
Rickettsia prowazekii
SARS coronavirus (SARS-CoV)
SARS–CoV/SARS–CoV–2 chimeric viruses resulting from any deliberate manipulation of SARS–CoV–2 to incorporate nucleic acids coding for SARS–CoV virulence factors.
Saxitoxin
South American hemorrhagic fever viruses:
Chapare
Guanarito
Junin
Machupo
Sabia
Staphylococcal enterotoxins (subtypes A–E)
T–2 toxin
Tetrodotoxin
Tick-borne encephalitis virus

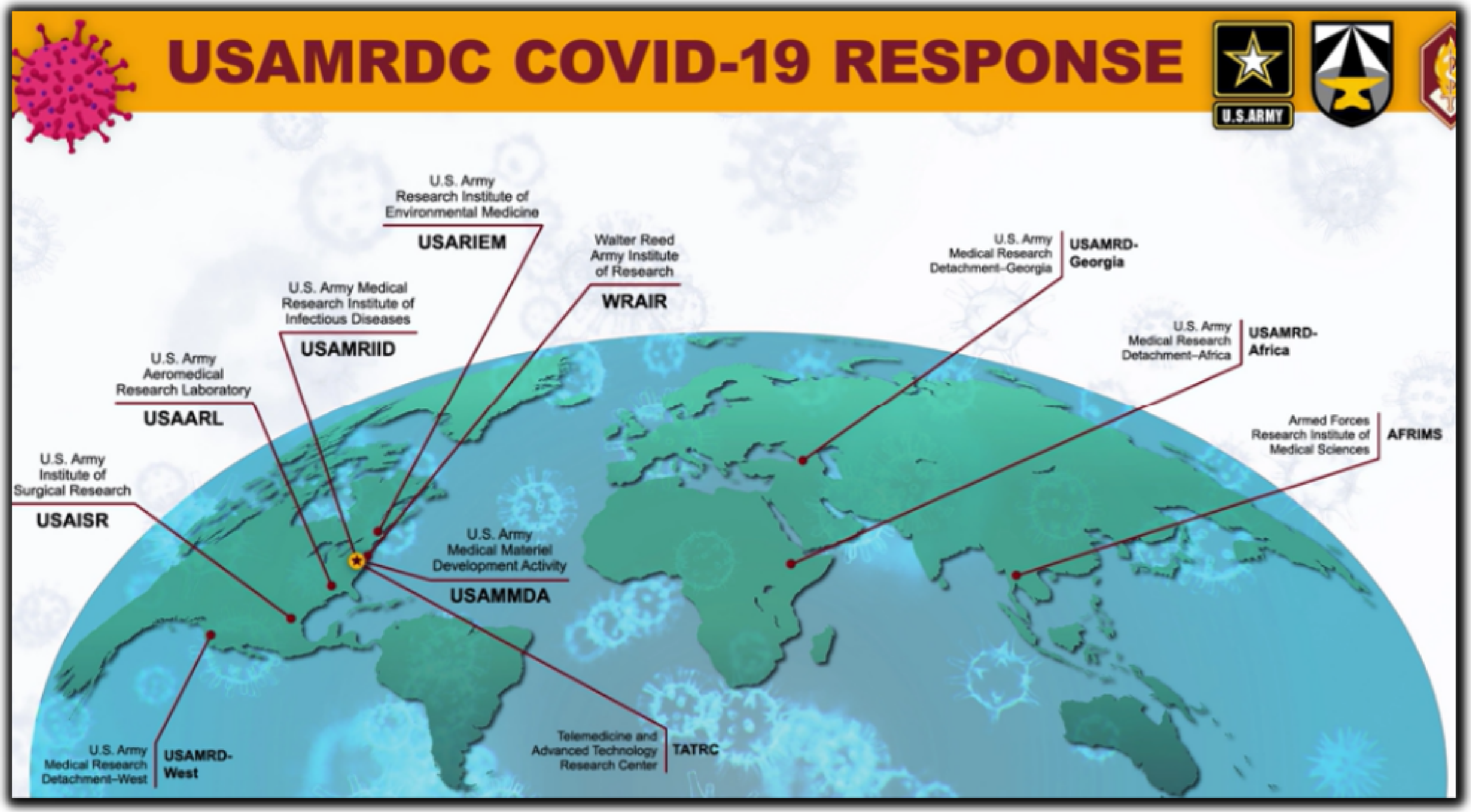
[1] C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges; The consensus sequence includes known toxins α-MI and α-GI (shown above) as well as α-GIA, Ac1.1a, α-CnIA, α-CnIB; X1 = any amino acid(s) or Des-X; X2 = Asparagine or Histidine; P = Proline; A = Alanine; G = Glycine; X3 = Arginine or Lysine; X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan; X5 = Tyrosine, Phenylalanine, or Tryptophan; X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine; X7 = Any amino acid(s) or Des X and; "Des X" = "an amino acid does not have to be present at this position." For example if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.

USAMRDC Covid-19 Guidance

Vaccine Development

- WRAIR produced the most detailed atomic-level view of the SARS-CoV-2 spike protein receptor binding domain, which is the part of the virus that binds to the lungs. This has been critical to vaccine discovery and development efforts, as it provides a resource map for the field in rationale vaccine design.
- USAMRDC is in full support of Operation Warp Speed, a coordinating effort to accelerate COVID-19 vaccine development.
- WRAIR down-selected a vaccine candidate from multiple prototypes based on an approach that has shown promise for other respiratory viruses, such as influenza.
- USAMRIID is performing foundational studies to establish validated small and large animal models for testing not only WRAIR's vaccine candidate but multiple vaccines and therapeutics in development. Animal efficacy testing will be done in parallel with human safety testing to accelerate vaccine development efforts.
- Phase I clinical trials for WRAIR's vaccine candidate remain on track to start screening potential human subjects in July, with the goal of starting vaccinations in September 2020 to evaluate the safety of the candidate vaccine.
- The Command is also partnering with government, academia, and industry to identify opportunities to leverage USAMRDC's full range of vaccine development competencies in support of accelerating the most promising vaccine candidates.

USAMRDC COVID-19 RESPONSE



USAMRDC COVID-19 RESPONSE



PREVENT

safe and effective vaccine...

Vaccine Development

- USAMRDC partners with government, academia, and industry to accelerate the most promising vaccine candidates through clinical trials

USAMRDC COVID-19 RESPONSE



DETECT

Diagnostics

- High throughput confirmatory
- Clearance assays to assist with return-to-duty recommendations
- Antibody immunoassays
- Portable point-of-care, rapid detection devices

USAMRDC COVID-19 RESPONS

TREAT

Therapeutics

- USAMRDC entered into a CRADA with Gilead Sciences to provide remdesivir to exposed DoD personnel



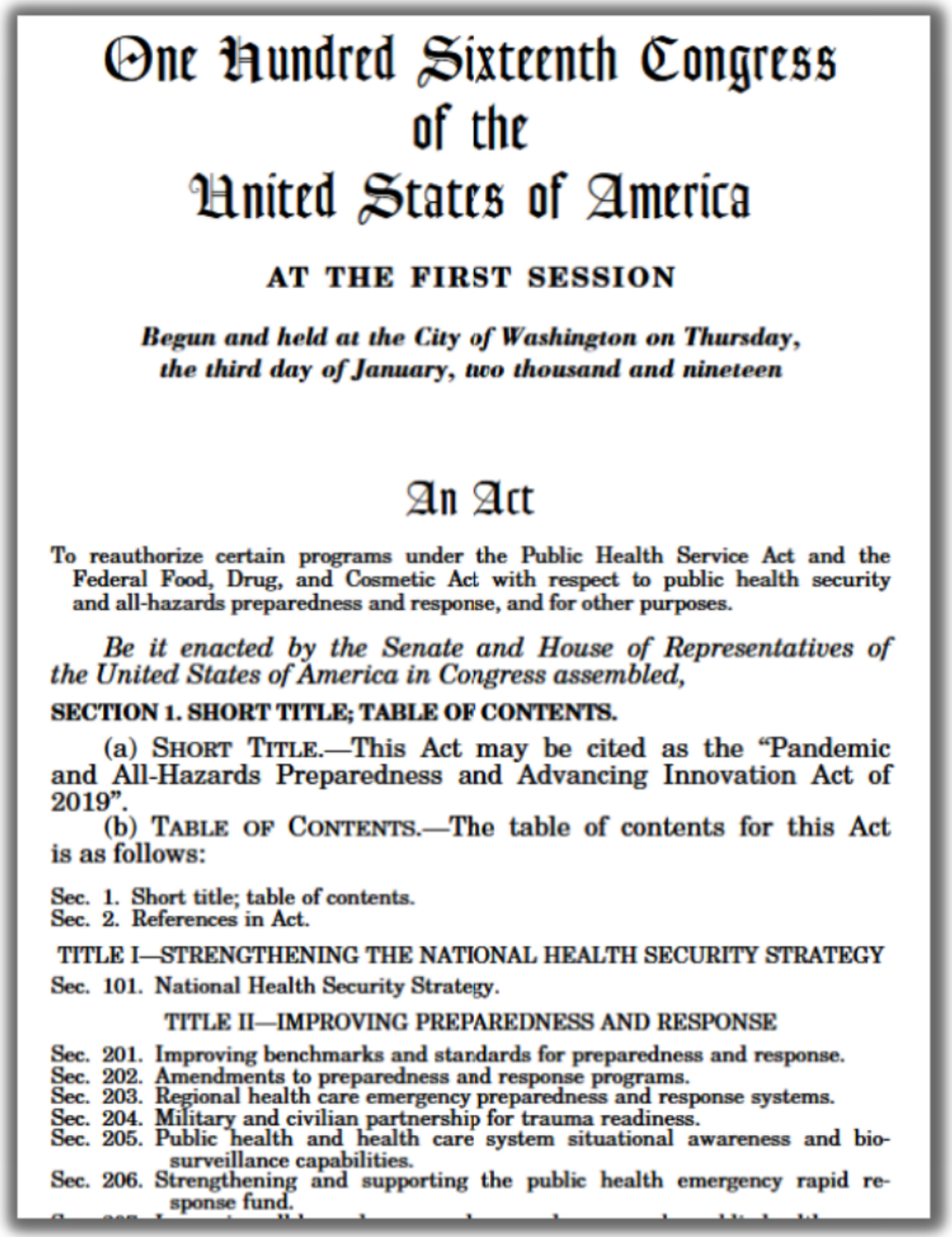
“Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAPHIA)

Jan 3, 2019

The Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019. It aims to improve the preparedness and response of the United States to public health emergencies. The document proposes several amendments to existing laws to achieve this goal. Some of the key amendments include:

- Improving coordination among federal, state, local, tribal, and territorial entities to prevent, detect, and respond to outbreaks of plant or animal disease that could compromise national security.
- Assessing current or potential health security threats from abroad to inform domestic public health preparedness and response capabilities.
- Evaluating evidence-based benchmarks and objective standards required under the law to track progress towards preparedness goals.
- Authorizing appropriations for public health security grants and the Partnership for State and Regional Hospital Preparedness.

Overall, the it aims to enhance the ability of the United States to respond to public health emergencies and protect the health and safety of its citizens.



One Hundred Sixteenth Congress
of the
United States of America

AT THE FIRST SESSION

Begun and held at the City of Washington on Thursday, the third day of January, two thousand and nineteen

An Act

To reauthorize certain programs under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to public health security and all-hazards preparedness and response, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the “Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019”.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. References in Act.

TITLE I—STRENGTHENING THE NATIONAL HEALTH SECURITY STRATEGY

Sec. 101. National Health Security Strategy.

TITLE II—IMPROVING PREPAREDNESS AND RESPONSE

Sec. 201. Improving benchmarks and standards for preparedness and response.
Sec. 202. Amendments to preparedness and response programs.
Sec. 203. Regional health care emergency preparedness and response systems.
Sec. 204. Military and civilian partnership for trauma readiness.
Sec. 205. Public health and health care system situational awareness and bio-surveillance capabilities.
Sec. 206. Strengthening and supporting the public health emergency rapid response fund.

“Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAPHIA)

One Hundred Sixteenth Congress
of the
United States of America

AT THE FIRST SESSION

Begun and held at the City of Washington on Thursday, the third day of January, two thousand and nineteen

An Act

To reauthorize certain programs under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to public health security and all-hazards preparedness and response, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the “Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019”.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

(2) in subsection (b), by striking "2010 through 2013" and inserting "2019 through 2023".

TITLE VII—MISCELLANEOUS PROVISIONS

SEC. 701. REAUTHORIZATIONS AND EXTENSIONS.

(a) VETERANS AFFAIRS.—Section 8117(g) of title 38, United States Code, is amended by striking "2014 through 2018" and inserting "2019 through 2023".

(b) VACCINE TRACKING AND DISTRIBUTION.—Section 319A(e) (42 U.S.C. 247d–1(e)) is amended by striking "2014 through 2018" and inserting "2019 through 2023".

(c) TEMPORARY REASSIGNMENT.—Section 319(e)(8) (42 U.S.C. 247d(e)(8)) is amended by striking "2018" and inserting "2023".

(d) STRATEGIC INNOVATION PARTNER.—Section 319L(c)(4)(E)(ix) (42 U.S.C. 247d–7e(c)(4)(E)(ix)) is amended by striking "2022" and inserting "2023".

(e) LIMITED ANTITRUST EXEMPTION.—

(1) IN GENERAL.—Section 405 of the Pandemic and All-Hazards Preparedness Act (Public Law 109–417; 42 U.S.C. 247d–6a note) is amended—

(A) in subsection (a)(1)(A)—

(i) by striking "Secretary of Health and Human Services (referred to in this subsection as the 'Secretary')" and inserting "Secretary";

(ii) by striking "of the Public Health Service Act (42 U.S.C. 247d–6b)) (as amended by this Act";

(iii) by striking "of the Public Health Service Act (42 U.S.C. 247d–6a)) (as amended by this Act"; and

(iv) by striking "of the Public Health Service Act (42 U.S.C. 247d–6d)";

(B) in subsection (b), by striking "12-year" and inserting "17-year";

(C) by redesignating such section 405 as section 319L–

"(2) The term 'medical countermeasure submission' means an investigational new drug application under section 505(i), a new drug application under section 505(b), or an abbreviated new drug application under section 505(j) of this Act, a biological product license application under section 351(a) of the Public Health Service Act or a biosimilar biological product license application under section 351(k) of the Public Health Service Act, a new animal drug application under section 512(b)(1) or abbreviated new animal drug application under section 512(b)(2), an application for conditional approval of a new animal drug under section 571, an investigational device application under section 520(g), an application with respect to a device under section 515(c), a request for classification of a device under section 513(f)(2), a notification with respect to a device under section 510(k), or a request for an emergency use authorization under section 564 to support—

"(A) the approval, licensure, classification, clearance, conditional approval, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product; or

"(B) a new indication to an approved security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product.

"(3) The terms 'qualified countermeasure', 'security countermeasure', and 'qualified pandemic or epidemic product' have

MOU 225-13-0028

MEMORANDUM OF UNDERSTANDING CONCERNING
INFORMATION-SHARING EXCHANGES INVOLVING FDA
AMONG AGENCIES PARTICIPATING IN THE
PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURE ENTERPRISE (PHEMCE)
OFFICES AND AGENCIES OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES:
OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL INSTITUTES OF HEALTH
FOOD AND DRUG ADMINISTRATION AND
THE DEPARTMENT OF DEFENSE
THE DEPARTMENT OF HOMELAND SECURITY
THE DEPARTMENT OF VETERANS AFFAIRS
THE DEPARTMENT OF AGRICULTURE

Content current as of:

04/09/2019

Preamble:

The Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) is a coordinated interagency effort which is responsible for, *inter alia*, focusing research, development, and procurement activities to provide medical countermeasures that will be safe and effective for use in the event of a public health or medical emergency. The PHEMCE is led by the Office of the Assistant Secretary for Preparedness and Response (ASPR) of the Department of Health and Human Services (HHS) and includes three primary HHS internal agencies: the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH). The Biomedical Advanced Research and Development Authority (BARDA) is also established within ASPR. The PHEMCE also includes other key federal partners: the Department of Homeland Security (DHS), the Department of Defense (DoD), including certain constituent components specified herein, the Department of Veterans Affairs (VA), and the Department of Agriculture. These offices, agencies, and Departments are thus considered and hereafter referred to in this document as PHEMCE Partners or Partners.

MOU 225-13-0028

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Domestic MOUs

MOU 225-22-029

MOU 225-22-024

MOU 225-22-026

MOU 225-23-001

MOU 225-23-003

MEMORANDUM OF UNDERSTANDING CONCERNING
INFORMATION-SHARING EXCHANGES INVOLVING FDA
AMONG AGENCIES PARTICIPATING IN THE
PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURE ENTERPRISE (PHEMCE)
OFFICES AND AGENCIES OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES:
OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL INSTITUTES OF HEALTH
FOOD AND DRUG ADMINISTRATION AND
THE DEPARTMENT OF DEFENSE
THE DEPARTMENT OF HOMELAND SECURITY
THE DEPARTMENT OF VETERANS AFFAIRS
THE DEPARTMENT OF AGRICULTURE

Content current as of:
04/09/2019

To promote efficiency and collaboration among and between FDA and PHEMCE Partners, by facilitating efforts to:

- Build a framework and processes that meet common needs for considering issues relating to the safety, efficacy, and utilization of drugs, biologics, and medical devices for use in emergencies, including response preparedness and planning.
- Further enhance efforts to share information and expertise through more efficient and robust inter-agency activities.
- Identify and develop enabling scientific tools and technologies that will support the ultimate development of useful medical products.
- Develop safe and effective medical countermeasures.
- Clarify FDA requirements applicable to medical countermeasure initiatives that are being sponsored by PHEMCE Partners.
- Exchange and share related information concerning medical and pharmaceutical countermeasures in real time or electronically in multiple media.
- Maintain appropriate, robust information and data security standards and practices.

MOU 225-22-029

MOU 225-22-024

MOU 225-22-026

MOU 225-23-001

MOU 225-23-003

2023 MOUs

V. General Provisions:

This is an internal Government agreement among the parties to this MOU and does not confer any rights or benefits to any person or party. This MOU does not include any commitment, by any Partner, of resource contributions or exchanges.

This MOU does not supersede any existing agreements or arrangements among the parties; to the extent the provisions of this MOU conflict with any existing or future agreement between FDA and any other individual PHEMCE Partner, the provisions of this MOU shall govern FDA communications relating to medical countermeasures for emergency use that involve multiple PHEMCE Partners. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which the parties operate, and nothing in the MOU shall be construed as changing the current requirements under the statutes and regulations administered and enforced by any Partner. Further, nothing contained in this MOU constitutes a mandate or a requirement imposed on any Partner that is additional to the mandates or requirements imposed on them, individually or collectively, by Federal statutes and regulations.

VI. Liaison Officers:

a. For the Food and Drug Administration:
Luciana Borio, M.D.
Director, Office of Counterterrorism and Emerging Threats
Office of the Chief Scientist
Office of the Commissioner
Food and Drug Administration
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Luciana Borio
In-Q-Tel
CFR
Inspiration for Government
Resilience Services
John Hopkins Graduate

e. While the DoD is the regulatory applicant/sponsor for many of its medical product development programs, the Parties acknowledge that for many DoD MPPs, the regulatory applicants/sponsors are non-governmental entities for which the product development is DoD-supported by a contract under 10 USC §2304 and §2358, other transaction authority (OTA) under 10 USC §2371a or §2371b; by a cooperative research and development agreement (CRADA) under 15 USC §3710a; by a grant or cooperative agreement under 10 USC §2358; or by an interagency agreement with another government agency under the Economy Act, 31 USC §1535; or alternatively, a memorandum of agreement (MOA). The Parties acknowledge that emergent issues could result in a product being placed on the Priority List without a pre-existing relationship between the applicant/sponsor and the DoD or when DoD's relationship with the applicant/sponsor is secondary to another federal government product developer (e.g., HHS Biomedical Advanced Research and Development Authority (*BARDA*)). When the regulatory applicant/sponsor of a product on the Priority List is a non-governmental entity, DoD will ensure that any information shared about that product is within DoD authority to share and/or such rights to disclose the information to FDA are obtained before disclosure. FDA will also require permission of the owner of such information before any disclosure is made to DoD and, accordingly, such permission may be granted to FDA using terms such as those contained within the model authorization at **Exhibit B**. When the regulatory applicant/sponsor of a product on the Priority List is a non-DoD governmental entity (e.g., BARDA), disclosure may be facilitated using other existing MOUs, such as under the terms of the Public Health Emergency Medical Countermeasure Enterprise MOU. [1]

OTA

CRADA

MOA

MOU

Pfizer and The Medicines Patent Pool (MPP) Sign Licensing Agreement for COVID-19 Oral Antiviral Treatment Candidate to Expand Access in Low- and Middle-Income Countries

Tuesday, November 16, 2021 - 06:45am

NEW YORK & GENEVA--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and the Medicines Patent Pool (MPP), a United Nations-backed public health organization working to increase access to life-saving medicines for low- and middle-income countries, today announced the signing of a voluntary license agreement for Pfizer's COVID-19 oral antiviral treatment candidate PF-07321332, which is administered in combination with low dose ritonavir (PF-07321332; ritonavir). The agreement will enable MPP to facilitate additional production and distribution of the investigational antiviral, pending regulatory authorization or approval, by granting sub-licenses to qualified generic medicine manufacturers, with the goal of facilitating greater access to the global population.

About MPP

The Medicines Patent Pool (MPP) is a United Nations-backed public health organization working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries. Through its innovative business model, MPP partners with civil society, governments, international organizations, industry, patient groups, and other stakeholders, to prioritize and license needed medicines and pool intellectual property to encourage generic manufacture and the development of new formulations. To date, MPP has signed agreements with eleven patent holders for thirteen HIV antiretrovirals, one HIV technology platform, three hepatitis C direct-acting antivirals, a tuberculosis treatment, a long-acting technology and two experimental oral antiviral treatments for COVID-19. MPP was founded by Unitaid, which continues to be MPP's main funder. MPP's work on access to essential medicines is also funded by the Swiss Agency for Development and Cooperation (SDC). MPP's activities in COVID-19 are undertaken with the financial support of the Japanese Government and SDC. More information at https://medicinespatentpool.org/ and follow us on Twitter, LinkedIn and YouTube.

MCDC
Medical CBRN Defense
CONSORTIUM

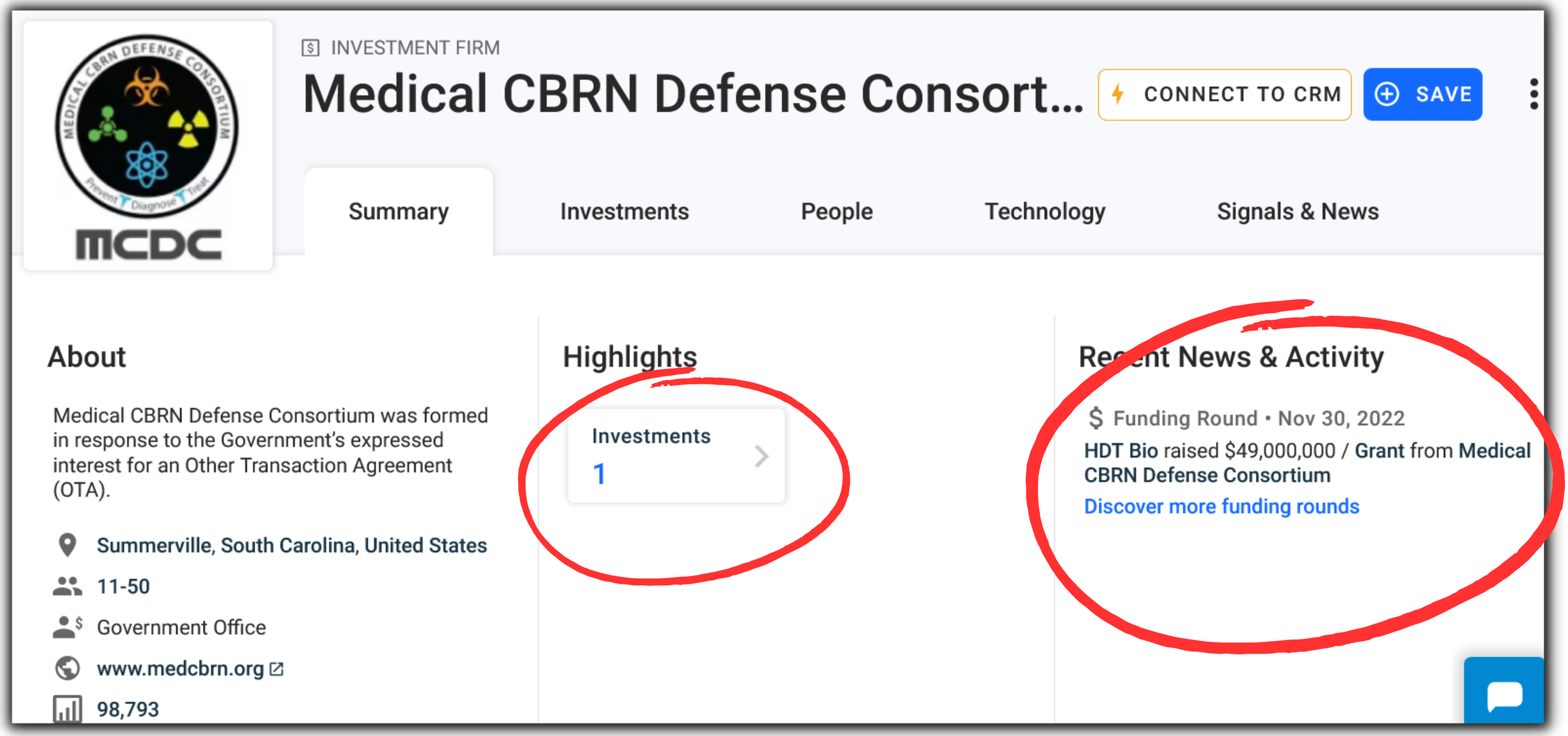
The OTA Consortium is an enterprise partnership between the US Government (MCS) and the MCDC connected through a "contract-like" OTA. This OTA operates outside the Federal Acquisition Regulations.

The MCDC provides the flexibility for better public and private collaboration by providing access to innovative concepts, ideas, and technologies from traditional and non-traditional technology providers. Through the OTA with the MCDC, the JPEO-CBRND and MCS are looking to work with new industry partners to provide soldiers with safe an effective medical countermeasures.

The MCDC is currently recruiting a broad and diverse group of interested parties that includes representatives from large businesses, small businesses, traditional and non-traditional government contractors, academic research institutions, and not-for-profit organizations with collective expertise in the technology areas specifically related to th JPEO-CBRND/MCS mission.

Example Technical Areas of Interest:

- Therapeutic MCM prototypes targeting viral, bacterial, and biological toxins and MCM enabling technologies
- Single and multiple-drug autoinjector delivery devices
- Vaccine-manufacturing platforms
- Prototypes for the prophylaxis, treatment and diagnosis of CBRN threats, including Acute Radiation Syndrome and chemical nerve agents
- Systems to increase the speed, accuracy, and confidence of agent identification and disease diagnosis
- Advanced development and manufacturing capabilities


INVESTMENT FIRM
Medical CBRN Defense Consort...
CONNECT TO CRM
SAVE
Summary
Investments
People
Technology
Signals & News
About
Medical CBRN Defense Consortium was formed in response to the Government's expressed interest for an Other Transaction Agreement (OTA).
Summerville, South Carolina, United States
11-50
Government Office
www.medcbrn.org
98,793
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Recent News & Activity
Funding Round • Nov 30, 2022
HDT Bio raised $49,000,000 / Grant from Medical CBRN Defense Consortium
Discover more funding rounds

Who We Are

The Medical CBRN Defense Consortium (MCDC) was formed in response to the Government's expressed interest to establish an Other Transaction Agreement (OTA) with an eligible entity or group of entities, to include industry, academic, and not-for-profit partners, for advanced development efforts to support the Department of Defense's (DoD) medical, pharmaceutical and diagnostic requirements a related to enhancing the mission effectiveness of military personnel.

Through the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND), the Medical Countermeasures Systems (MCS) Joint Project Management Office is always looking for innovative, safe and effective medical solution to counter CBRN threats. The usage of an OTA allows government to partner with the MCDC to leverage cutting edge R&D and develop prototypes from commercial sources. This gives MCS an agile and flexible way to develop medical countermeasures using new and innovative technology.

The OTA Consortium is an enterprise partnership between the US Government (MCS) and the MCDC connected through a "contract-like" OTA. This OTA operates outside the Federal Acquisition Regulations.

The MCDC provides the flexibility for better public and private collaboration by providing access to innovative concepts, ideas, and technologies from traditional and non-traditional technology providers. Through the OTA with the MCDC, the JPEO-CBRND and MCS are looking to work with new industry partners to provide soldiers with safe and effective medical countermeasures.

medicines patent pool

"The Medicines Patent Pool was established as a landmark initiative to expand access to treatments for priority diseases. Over the last decade, MPP has become a strong partner in global health, working to facilitate access to HIV and hepatitis C medicines in low- and middle-income countries through voluntary licensing and patent pooling. With its impressive track record, MPP has a critical role to play in making affordable versions of patented essential medicines and technologies available to those who need it the most, including for COVID-19."

Dr Tedros Adhanom Ghebreyesus, Director-General, World Health Organization

MPP in Numbers

18 patent holders with MPP signed agreements

55 generic manufacturers and product developers have sublicences from MPP

26.91 Bn doses of treatment supplied (Jan 2012 - Dec 2021)

US$1.2 Bn dollars saved through MPP'S licences (Jan 2012 - Dec 2021)

By 2030

US$3.5 Bn

projected dollars saved

148 countries have benefited from access to MPP-licensed products

71.76 Mn patient-years of treatment through MPPs generic partners (Jan 2012 - Dec 2021)

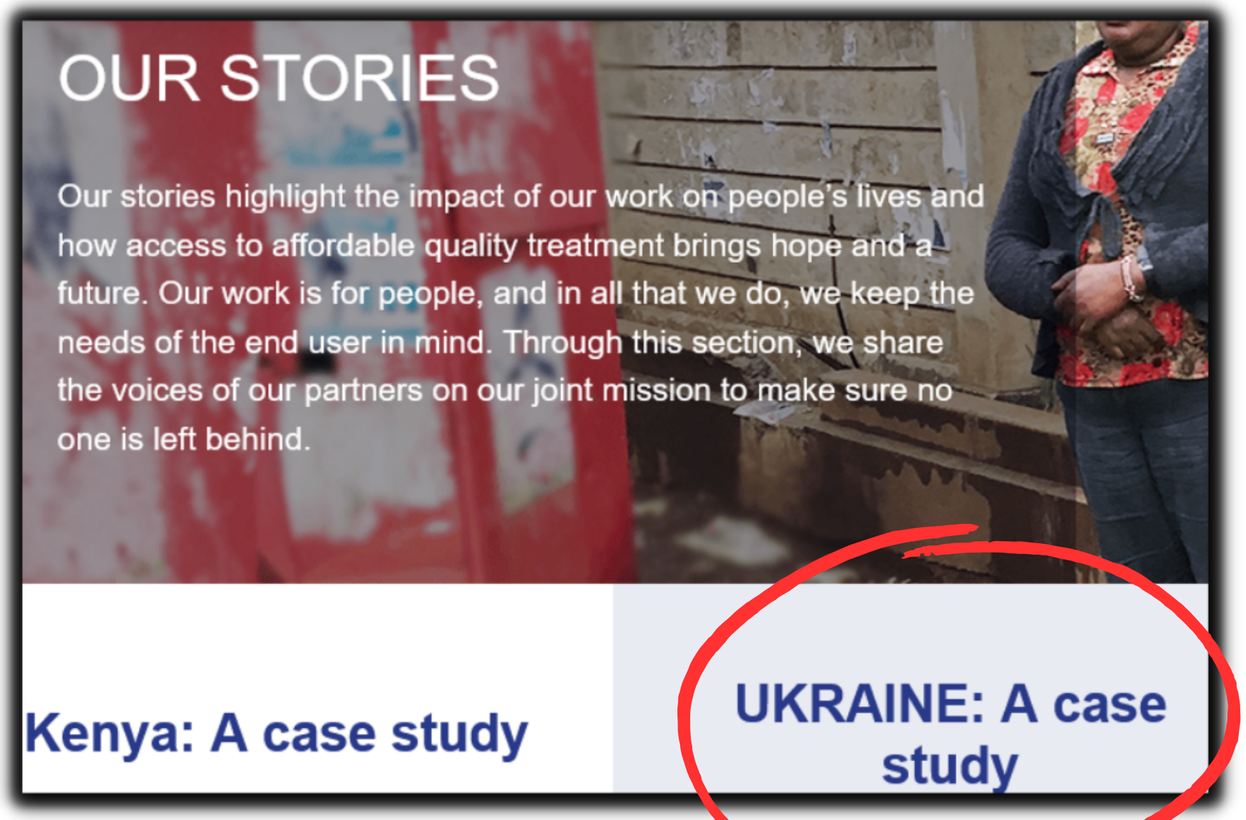
18,000 deaths averted (Jan 2012 - Dec 2021)

By 2030

160,000

deaths averted

MPP & Ukraine



Making HIV and viral hepatitis treatments accessible

Ukraine has the second largest HIV epidemic in Eastern Europe and Central Asia. And nearly 1.5 million people in the country are living with hepatitis C.

How do you get affordable quality medicines to these people in need?

This January, MPP visited Ukraine to engage with partners – from patients to medical experts, from originators to generic manufacturers, from civil society to the WHO and many more. Unleashing the power of partnership, MPP's licences have led to the supply of over 20,000 courses of hepatitis C treatments and 1.5 million packs of DTG and combination products for HIV treatment in Ukraine.

medicines patent pool

mRNA Scientific Advisory Committee (mSAC)

The mRNA Scientific Advisory Committee (mSAC) is an independent committee convened by the Medicines Patent Pool (MPP) to deliver answers, on a consultative basis, to specific questions on scientific matters addressed to them relating to the mRNA Technology Transfer Hub Programme.

mRNA Scientific Advisory Committee Members:

Composition of m-SAC as of September 2022, with more members coming soon



Martin Friede, Ph.D.
Coordinator, Initiative for Vaccine Research at the World Health Organization
(mSAC Chair)



Dr. Danilo Casimiro, Ph.D.
Chief Science Officer & Global Head, External Scientific Affairs, Sanofi Vaccines



Barney Graham, M.D., Ph.D.
Former Deputy Director of the Vaccine Research Center at the National Institutes of Health and the Chief of the Viral Pathogenesis



Drew Weissman, M.D., Ph .D.
MD, PhD, Co-Director, Penn Center for AIDS Research, Immunology Core Director of Vaccine Research, Infectious Diseases Division



Duccio Medini, Ph.D.
R3 Program Director at Wellcome Leap, global ARPA for Health, and Strategic Data Science Director at Toscana Life Sciences Foundation, Siena (Italy).



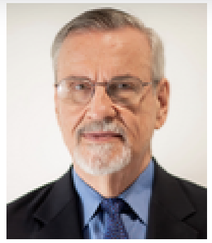
Dr. Connie Schmaljohn
Director, NIAID Integrated Research Facility (IRF-Frederick)



Suhaib Siddiqui, Ph.D.
Former director of chemistry at Moderna Founder of Antirna Inc



Kiat Ruxrungtham, M.D.
Professor of Medicine, Department of Medicine Chulalongkorn University; and Scientific Chair of the Chula Vaccine Research Center



Barney Graham, M.D., Ph.D.

Former Deputy Director of the Vaccine Research Center at the National Institutes of Health and the Chief of the Viral Pathogenesis Laboratory.

Dr. Graham is the former Deputy Director of the NIAID Vaccine Research Center and has developed novel vaccines and monoclonal antibodies for several viral diseases including the COVID-19 mRNA vaccine for which he has been widely recognized.

Barney S. Graham is an immunologist, virologist, and clinical trials physician with an extensive background in basic and translational research applied to vaccine development. He obtained an undergraduate degree from Rice University, a medical degree from the University of Kansas, and residency, ID fellowship, and PhD from Vanderbilt University where he was an R01-funded investigator before joining the NIAID Vaccine Research Center at NIH as a founding member in 2000. He retired as Deputy Director of the VRC in 2021 and is now an independent consultant and Senior Advisor for Global Health Equity at Morehouse School of Medicine in Atlanta.

He is an elected member of ASCI, AAP, and National Academy of Sciences. He is recipient of the Robert M. Chanock Award for lifetime contributions to RSV research, the Albert B. Sabin Gold Medal Award for contributions to vaccinology, the Albany Medical Center Prize in Medicine and Biomedical Research, and the National Academy of Sciences John J. Carty Award for the Advancement of Science. He was named one of the world's 100 most influential individuals and one of the Heroes of the Year in 2021 by Time magazine and recognized as the Federal Employee of the Year by the Partnership for Public Service.

He is an author on more than 500 scientific publications, and a thought leader on emerging viral diseases and pandemic preparedness. He is best known for his research on RSV pathogenesis, structure-based vaccine design, and application of mRNA delivery technology. He was involved in the advanced evaluation of vaccines and monoclonal antibodies for HIV, Ebola, and Chikungunya, and developed novel vaccines for RSV, influenza, Zika, paramyxoviruses, and coronaviruses including the first COVID-19 vaccine and monoclonal antibody to enter clinical testing and that subsequently achieved Emergency Use Authorization and licensure.

NIAID, NIH, Vaccine Research Center, mAbs,



Drew Weissman, M.D., Ph .D.

mRNA Scientific Advisory Committee (mSAC)

MD, PhD, Co-Director, Penn Center for AIDS Research, Immunology Core Director of Vaccine Research, Infectious Diseases Division

Drew Weissman, M.D., Ph.D. is a professor of Medicine at the Perelman School of Medicine, University of Pennsylvania. He received his graduate degrees from Boston University School of Medicine. Dr. Weissman, in collaboration with Dr. Katalin Karikó, discovered the ability of modified nucleosides in RNA to suppress activation of innate immune sensors and increase the translation of mRNA containing certain modified nucleosides. The nucleoside-modified mRNA-lipid nanoparticle vaccine platform Dr. Weissman's lab created is used in the first 2 approved COVID-19 vaccines by Pfizer/BioNTech and Moderna. They continue to develop other vaccines that induce potent antibody and T cell responses with mRNA–based vaccines. Dr. Weissman's lab also develops methods to replace genetically deficient proteins, edit the genome, and specifically target cells and organs with mRNA-LNPs, including lung, heart, brain, CD4+ cells, all T cells, and bone marrow stem cells.

Covid-19 Vaccine; Pfizer + Moderna



Suhaib Siddiqui, Ph.D.

Former director of chemistry at Moderna Founder of Antirna Inc

Suhaib Siddiqi is a scientist in the field of infectious diseases, nucleic acids and genomics. As a head of the departments, he led the research and development efforts at various biotechnology and pharmaceutical companies. He was the first director of chemistry at Moderna.

He has a doctorate in Chemistry from the University of Technology, Vienna, Austria. He currently serves as a scientific advisor to various biotechnology companies. He was inventor of a potent antiviral agent (-)-5'-Noraristeromycin and Virtual Terminators for the DNA/RNA sequencing. He has published 31 peer-reviewed papers and 47 patents

Moderna



Kiat Ruxrungtham, M.D.

Professor of Medicine, Department of Medicine Chulalongkorn University; and Scientific Chair of the Chula Vaccine Research Center

Kiat Ruxrungtham, MD, is a Professor of Medicine, Department of Medicine, Faculty of Medicine, Chulalongkorn University; and Scientific Chair of the Chula Vaccine Research Center (ChulaVRC); and Director of the Covid19 Vaccine Development Program, ChulaVRC. He is providing teaching and patient care on Allergy -Clinical Immunology and HIV Medicine at the King Chulalongkorn Memorial Hospital, Faculty of Medicine, Chulalongkorn University; and is mentoring junior researchers on HIV medicine, vaccine, immunology, and allergy research and also on clinical trials. He is currently leading the Chula-Covid19 mRNA vaccine development program. He has published more than 360 peer review papers on HIV, immunology, allergy, and vaccine.

Chula-Covid-19 Vaccine, Chula VRC



Martin Friede, Ph.D.

Coordinator, Initiative for Vaccine Research at the World Health Organization

(mSAC Chair)

mRNA Scientific Advisory Committee (mSAC)

Friede is the scientific officer responsible for vaccine delivery systems within the Initiative for Vaccine Research (IVR) at the World Health Organization in Geneva, Switzerland. In this position he is the WHO focal point for matters related to the development of technologies to improve vaccines including adjuvants, stabilization methods needle-free vaccine delivery systems.

Prior to joining WHO Dr Friede held several positions in the vaccine industry: He was Vice President of Development for Apovia Inc. a Californian vaccine development company, prior to which he was responsible for vaccine formulation and vaccine delivery research at Smithkline Beecham Biologicals (now GlaxoSmithKline).Martin Friede received his PhD in biochemistry from the University of Cape Town in South Africa.

World Health Organization



Dr. Danilo Casimiro, Ph.D.

Chief Science Officer & Global Head, External Scientific Affairs, Sanofi Vaccines

Danilo is Chief Science Officer and Global Head, External Scientific Affairs for Sanofi Vaccines since October 2021. He is responsible for external-facing functions of the Vaccines R&D unit, including teams for search-and-evaluation of vaccine candidates and vaccine innovations, scientific network development & partnerships, and external financing. He has over 25 years of experience in research and development of vaccines and biologics in both pharmaceutical and non-profit sectors. Prior to joining Sanofi in November 2017, he was the Chief Scientific Officer at Aeras, a non-profit vaccine R&D organization funded by the Bill and Melinda Gates Foundation. During his 19 years at the Merck Research Laboratories, Danilo contributed to the licensure of Merck's human papillomavirus (HPV) vaccines, and the development of novel vaccine candidates and antibodies against multiple viral pathogens and novel immunotherapeutic approaches against cancer and neurodegenerative diseases. He also served on numerous advisory committees to the Bill & Melinda Gates Foundation Global Health Program, International AIDS Vaccine Initiative, NIH Integrated Preclinical/Clinical AIDS Vaccine Development Program, USAID Malaria Vaccine Development Program, and HIV Vaccine Enterprise. He received his Ph.D. degree in chemistry and post-doctoral training from the California Institute of Technology and the Scripps Research Institute-La Jolla, respectively.

Bill and Melinda Gates Foundation, Sanofi, Scripps Research Institute, USAID, Merck,



Duccio Medini, Ph.D.

mRNA Scientific Advisory Committee (mSAC)

R3 Program Director at Wellcome Leap, global ARPA for Health, and Strategic Data Science Director at Toscana Life Sciences Foundation, Siena (Italy).

Duccio Medini leads the 60M$ RNA Readiness and Response program, co-funded by CEPI, to develop standardized, multi-product RNA manufacturing capabilities providing increased access to diverse biologics and sustainable pandemic response.

In executive roles of growing responsibility at Chiron, Novartis and GSK corporations, he led hundreds of data scientists in Vaccines R&D across Europe, US and Asia, holding Research Board, Innovation Board, Clinical Quality Board and Data Governance Board responsibilities.

Working across biological discovery, clinical development and public health, he discovered the pangenome concept co-founding the pangenomics discipline, contributed to the successful registration of four novel vaccines, including the first universal vaccine against serogroup B meningitis, led the Meningococcal Antigen Typing System (MATS) platform worldwide, developed transformative corporate data strategies, authored 50+ publications, books and patents in data science for health, population genomics and mathematical vaccinology.

Prof. Medini received his Ph.D. in Physics from the University of Perugia, Italy, with a residency at the Northeastern University in Boston, MA; is habilitated Full Professor of Molecular Biology; has served in international PhD school committees at the Perugia and Turin Universities in Italy; is honorary member of the Cuban Immunology Society, Fellow of the ISI Foundation, Strategic Board member of CINI's Italian National Digital Health Lab; an IMD, ADVAC and UC Berkley alumnus.

CEPI, GSK, Novartis



Dr. Connie Schmaljohn

mRNA Scientific Advisory Committee (mSAC)

Director, NIAID Integrated Research Facility (IRF-Frederick)

Dr. Connie Schmaljohn is the Director of the NIAID Integrated Research Facility (IRF-Frederick) where she provides overall scientific leadership to research activities and oversees collaborative research programs to advance medical countermeasures for highly pathogenic viruses. In addition, she serves as an expert consultant and advisor both nationally and internationally on the development of novel vaccine strategies for highly pathogenic viruses.

Dr. Schmaljohn earned a BS Degree in Microbiology from the University of Nebraska and a PhD in Virology from Colorado State University, after which she joined United States Army Medical Research Institute of Infectious Diseases (USAMRIID) as a National Research Council postdoctoral fellow. She continued her career at USAMRIID in multiple capacities culminating with a position as the Senior Research Scientist for Medical Defenses against Infectious Disease Threats for the US Army. Dr. Schmaljohn's research background is in molecular virology and molecular vaccine development. She has served as President of the International Society of Hantaviruses, Chair of the American Society for Microbiology Biodefense Conference, and Chair of the International Committee on the Taxonomy of Viruses Bunyaviridae Study Group. She also has served on the Interagency Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Viral Hemorrhagic Fevers IPT, the Board of Scientific Counselors for the NIAID Vaccine Research Center, the Scientific Advisory Council for the Coalition of Emergency Preparedness Innovations (CEPI) and the Independent Product Group (IPG) for COVAX. She was elected to the American Academy of Microbiology (2007) and was selected as Fellow of the International Society for Vaccines (2015). She received the Order of Military Merit (2002), the Association of Military Surgeons of the United States Research Award (2002), the University of Nebraska Alumni Achievement Award (2012), and the Presidential Rank Award (2017). Dr. Schmaljohn has published more than 200 peer reviewed journal articles and reference works, has edited many books and special journal issues and holds numerous patent awards for vaccine development efforts.

CEPI, USAMRIID, COVAX, PHEMCE, NIAID

Small Organization Members

Alchem Laboratories Corp. *
Aleph Therapeutics, Inc. *
Allied Technologies and Consulting, LLC
Allotropic Tech *
Altimmune, Inc. *
Amaratek *
AN2 Therapeutics, Inc. *
ANP Technologies, Inc. *
Arcturus Therapeutics *
EpiVax, Inc. *
eSpin Technologies, Inc. *
EverGlade Pharmaceuticals *
Evrys Bio, LLC *
Federal Resource Supply Company *
First Line Technology, LLC *
Flow Pharma, Inc. *
Foothold Labs, Inc. *
Fry Laboratories, LLC *
GenArraytion, Inc. *
Genovac Antibody Discovery *
GeoVax, Inc. *
Ginkgo Bioworks *
Government Scientific Source (GSS) *
iBio CDMO LLC *
iBio, Inc. *
IDBiologics, Inc. *
ImmunityBio, Inc. *
Immunome, Inc. *
INanoBio Inc. *
InBios International, Inc. *
Inovio Pharmaceuticals *
Integrated Biotherapeutics *
Integrated Solutions for Systems *
Intelligent Optical Systems *
Interlog Corporation *
Invenra Inc. *
InvivoSciences *
ITL LLC dba ITL Solutions *
Janus-I Science, Inc. *
JGW International dba JGW Group
Joint Research & Development, Ir
Just-Evotec Biologics, Inc. *
JYANT Technologies, Inc. *
Kaleo, Inc. *
Kleo Pharmaceuticals *
Koniku, Inc. *
Kytopen Corporation *
Latham BioPharm Group *
Lauren Sciences *
Lexem Strategy LLC dba Project M
Locus Biosciences *
Lumen Bioscience, Inc. *
Microbiotix, Inc.
MicroHealth, LLC *
Molecular Technologies Laboratories LLC*
Murtech, Inc. *
Najit Technologies, Inc. *
Nanobiofab *
NaNotics, LLC *
Mapp BioPharmaceutical, Inc. *
Materials Modification, Inc. *
Maxim Biomedical, Inc. *
Medigen, Inc. *
Medinstill Development LLC *
MedsForAll, Inc. *
Mesa Science Associates *
Meso Scale Diagnostics, LLC *
Microbiotix, Inc.
MicroHealth, LLC *
Molecular Technologies Laboratories LLC*
Murtech, Inc. *
Najit Technologies, Inc. *
Nanobiofab *
NaNotics, LLC *
Novavax, Inc. *
Novici Biotech LLC *
NovoBiotic Pharmaceuticals, LLC *
NUES, Inc. *
NuMat Technologies, Inc. *
Nutra Pharma Corporation *
OCMS Bio, LLC *
Ology Bioservices *
Paratek Pharmaceuticals *
Partner Therapeutics, Inc. *
Pathology Assist-Temp, Inc. *
Pertexa Healthcare Technologies, Inc. *
PharmaJet *
Pirouette Medical, LLC *
PlantVax, Inc. *
Polaris Sensor Technologies *
POP Biotechnologies, Inc. *
Primmune Therapeutics, Inc. *
Public Health Vaccines, LLC *
Ridgeback Biotherapeutics *
Rubix LS *
SAb Biotherapeutics, Inc. *
SafetySpect, Inc. *
Sanaria, Inc. *
SaponiQx, Inc.*
Scarab Genomics, LLC *
SciTech Services, Inc. *
Selva Therapeutics, Inc. *
Sentinel Analytics Software, Inc. *
SGSD Partners LLC *
Silver Lake Research Corporation *
Synthetic Genomics Vaccines Inc. *
Talis Biomedical Corporation *
TAMR, Inc. *
Tech62 *
Tetracore Inc. *
TFF Pharmaceuticals, Inc. *

Academic Members

- Boston University *
- Duke University
- Emory University *
- George Mason University
- Icahn School of Medicine at Mount Sinai *
- Indiana University *
- Iowa State University of Science and Technology *
- Northern Arizona University
- The Washington University *
- University of Arizona *
- University of California, Irvine *
- University of California, Los Angeles *
- University of Delaware on behalf of NIIMBL
- University of Florida, Institute for Therapeutic Innovation *
- University of Louisville *
- University of Maryland
- University of Massachusetts Lowell *
- University of Nebraska Medical Center
- University of Nebraska at Omaha *
- University of Nevada, Reno *
- University of New Mexico, Health Sciences Center *
- University of North Carolina at Chapel Hill (UNC) *
- University of Pittsburgh *
- University of Tennessee Health Science Center*
- University of Texas Medical Branch *
- Vanderbilt University Medical Center *
- Virginia Tech Applied Research Corporation *
- Wake Forest University Health Sciences

Non-Profit Members

- American Type Culture Collection *
- Battelle Memorial Institute *
- California Institute for Biomedical Research
- CUBRC, Inc. *
- Draper Labs (The Charles Stark Draper Laboratory, Inc.)
- Dyne Immune Institute for Translational Medicine and Research
- Global Pandemic Prevention and Biodefense Center, Inc. *
- IIT Research Institute
- Infectious Disease Research Institute (IDRI)
- International AIDS Vaccine Initiative (IAVI) *
- Mesa Tech International *
- MRIGlobal
- National Strategic Research Institute
- Quantum Leap Healthcare Collaborative *
- Sabin Vaccine Institute *
- Southwest Research Institute (SWRI)
- SRI International
- Texas Biomedical Research Institute
- The Geneva Foundation
- The Henry M. Jackson Foundation for the Advancement of Military Medicine
- The Wistar Institute
- Unify R&D *

Large Organization Members

- Advanced Bioscience Laboratories, Inc. (ABL) *
- Aldevron, LLC *
- Amentum Services, Inc.
- Applied Research Associates, Inc.
- AstraZeneca Pharmaceuticals, LP *
- BDO USA LLP *
- BioFire Defense, LLC *
- Booz Allen Hamilton
- Cepheid *
- Chemring Sensors & Electronic Systems, Inc.
- Conductive Technologies, Inc.
- Curia Global, Inc. *
- Emergent BioSolutions (Emergent Product Development Gaithersburg, Inc.)
- FLIR Detection, Inc. *
- General Atomics
- General Dynamics Information Technology, Inc. (GDIT)
- General Electric Company, GE Global Research
- Grifols Shared Services NA, Inc. *
- ICON Government and Public Health Solutions, Inc. *
- Innovative Emergency Management, Inc. (IEM) *
- International Business Machines Corp. (IBM)
- Janssen Research & Development LLC *
- Leidos Inc.
- MeMed US Inc.*
- Meridian Medical Technologies, Inc.
- Microsoft Corporation *
- Noblis, Inc.
- Patricio Enterprices, Inc. *
- Pfizer, Inc. *
- Pharm-Olam International *
- Polaris Alpha Advanced Systems, Inc. *
- PPD Development
- Qorvo Biotechnologies, LLC *
- Regeneron Pharmaceuticals, Inc. *
- Rigel Pharmaceuticals *
- Sanofi Pasteur VaxDesign Corporation *
- Schrödinger LLC
- SHL Pharma, LLC *
- SIGA Technologies, Inc. *
- Social & Scientific Systems, Inc. *
- Teledyne Brown Engineering, Inc.

International Participation: Membership in MCDC is limited to US companies or US-based affiliates of foreign companies. Foreign companies cannot gain membership due to MCDC's requirement that members obtain a DD2345 (military critical technical data agreement). However, foreign companies can be subcontractors (team members) on projects awarded through the Other Transaction Agreement (OTA) as long as they can meet the terms and conditions of the OTA. The MCDC member awarded the project is responsible for flowing the applicable requirements down to the foreign company.

CONTACT US:

MCDC@ati.org

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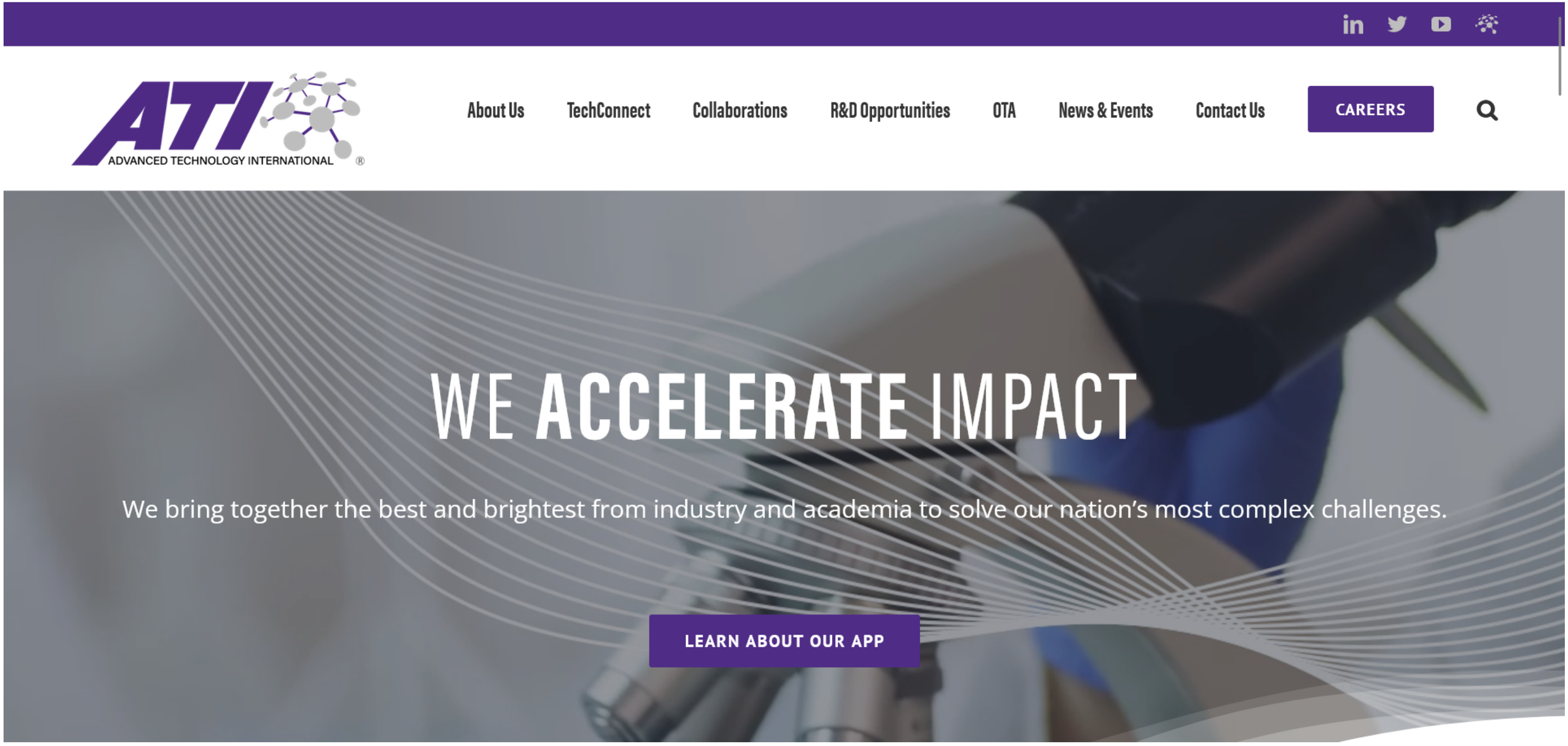
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ADVANCED TECHNOLOGY INTERNATIONAL

Trailing 12 Months
Fiscal Year

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Overview

Transactions Over Time

Top 5

The set of tables below provide a summary of awards to this recipient through multiple angles. To see more than the top 5, you can visit our Advanced Search page.

Awarding Agencies

Name	Awarded Amount	% of Total
1. Department of Defense (DOD)	$42.86M	100%

Awarding Sub-Agencies

Name	Awarded Amount	% of Total
1. Department of the Navy (USN)	$34.27M	79.95%
2. Department of the Air Force (U…	$8.18M	19.08%
3. Defense Logistics Agency (DLA)	$420,000	0.98%

Awarding Agencies

Name	Awarded Amount	% of Total
1. Department of Defense (DOD)	$42.86M	100%

Assistance Listings (CFDA Programs)

Name	Awarded Amount	% of Total
1. 12.114 - Collaborative Researc…	$8.23M	19.19%
2. 12.800 - Air Force Defense Rese…	$8.18M	19.08%

NAICS Codes

Name	Awarded Amount	% of Total
1. 541712 - Research and Develo…	$10.54M	24.6%
2. 541715 - Research and Develo…	$9.35M	21.82%
3. 541330 - Engineering Services	$6.55M	15.29%
4. 541710 - Research and Develo…	$8,189	0.02%

Product Service Codes

Name	Awarded Amount	% of Total
1. AE33 - R&D- ECONOMIC GROW…	$13.40M	31.27%
2. R425 - SUPPORT- PROFESSION…	$6.55M	15.29%
3. AC13 - R&D- DEFENSE SYSTEM:…	$5.48M	12.78%
4. AD23 - R&D- DEFENSE OTHER: …	$420,000	0.98%

ADVANCED TECHNOLOGY INTERNATIONAL

Also known by 4 other names

This recipient is associated with multiple parents in the dataset:
ANALYTIC SERVICES INC
ADVANCED TECHNOLOGY INTERNATIONAL(025172953)
Hide

CHILD RECIPIENT

42.9 Million in Government spending

Total Awarded Amount

$42.9 Million

from 144 transactions

View awards to this recipient

Face Value of Loans

$0

from 0 transactions

Details

Recipient Identifier	LDMMF472BB93 (UEI) 025172953 (Legacy DUNS)
Address	315 SIGMA DR SUMMERVILLE, SC UNITED STATES 7790
Congressional District	SC-01
Business Types	Business Corporate Entity Tax Exempt Nonprofit

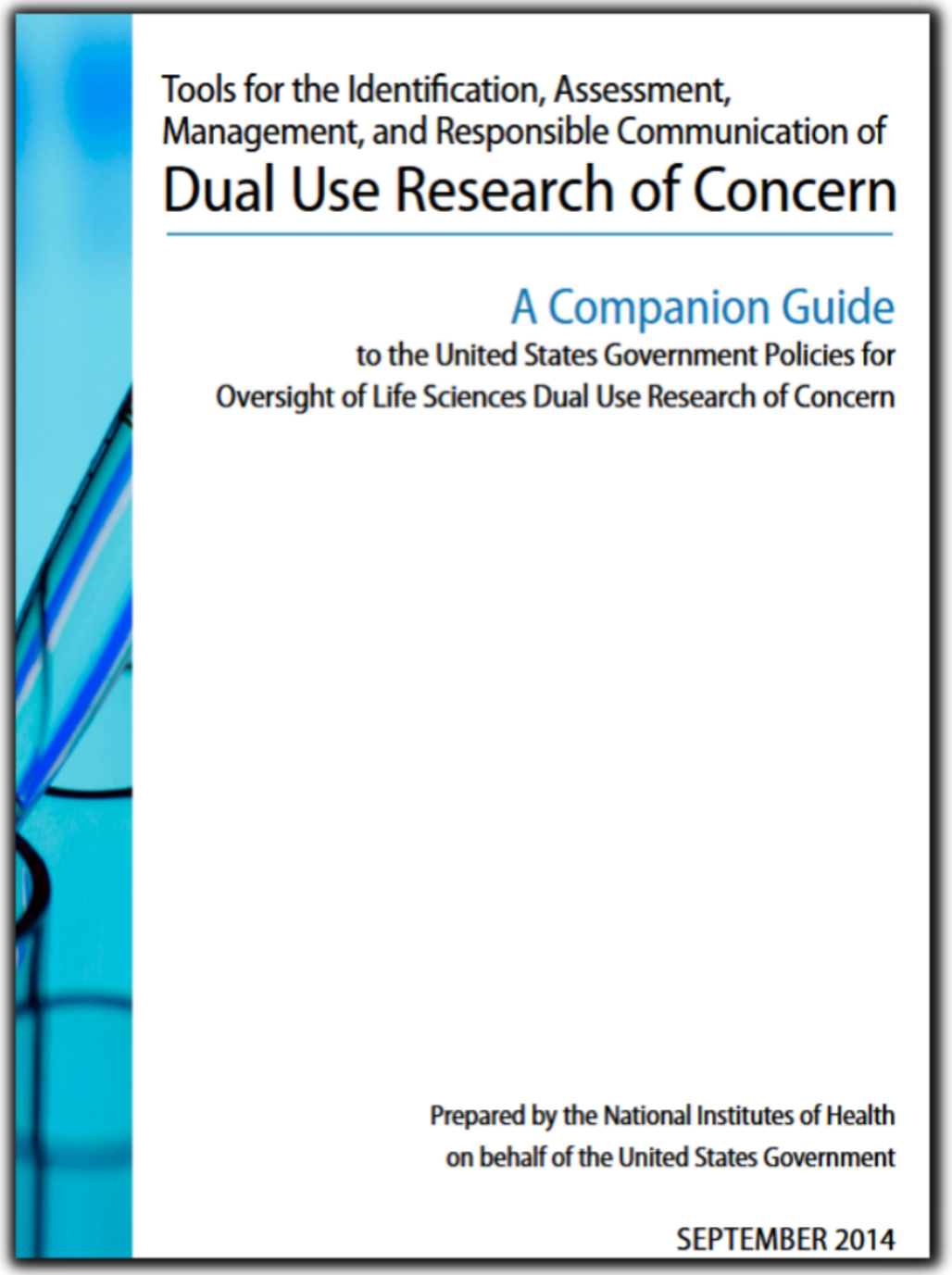
1. MOU 225-13-013, Concerning Information-Sharing Exchanges Involving FDA Among Agencies Participating in the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE).

2. DoD Partners include the U.S. Army Medical Research and Materiel Command (USAMRMC), the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND), Joint Science and Technology Office (JSTO) of the Defense Threat Reduction Agency (DTRA), the Defense Advanced Research Projects Agency (DARPA), and other DoD entities.

ii.Requests FDA to take action to expedite the development of such medical products, and the review of investigational submissions, applications for approval/licensure, and submissions/notifications for clearance of such medical products reasonably likely to diagnose, prevent, treat, or mitigate a specific and life-threatening risk to the U.S. military, including those for which emergency access is needed; or

iii. Seeks assistance in resolving a cross-cutting matter of regulatory science or policy.

d. The Priority List will provide for each listed MPP information substantially similar in content and format to **Exhibit A**, Model DoD Priority List Elements, including current regulatory applicant/sponsor information. The MPPs will be ranked by their priority and the Priority List may be expressed in a "1-n" format, by adjectival ratings, and/or be organized by the FDA center of jurisdiction as the Parties deem appropriate.



U.S. Government Gain-of-Function Deliberative Process and Research Funding Pause on Selected Gain-of-Function Research Involving Influenza, MERS, and SARS Viruses

Frequently Asked Questions

November 2014

National Science Foundation
WHERE DISCOVERIES BEGIN

NSF 17-1 January 30, 2017

Chapter XI - Other Post Award Requirements Considerations

5. Life Sciences Dual Use Research of Concern (DURC)

a. Applicability

This section applies to all research, for which NSF grant funds may be used, that potentially falls within the scope of the *US Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern* (http://www.phe.gov/s3/dualuse/Pages/default.aspx) as published in September 2014, hereafter referred to as the "Policy".

b. Policy

NSF is committed to preserving the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research. The purpose to NSFi¿½s implementation of this Policy is to clarify grantee expectations about NSF-funded research with certain high-consequence pathogens and toxins with potential to be considered dual use research of concern.

Grantees are responsible for monitoring the research progress and for implementation of all appropriate biosafety and biosecurity risk mitigation measures including compliance with all applicable laws and regulations related to that implementation, including the Policy specified above. (See also http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-concern for Frequently Asked Questions, case studies, and other educational materials on DURC.)

Jan 30, 2017

(d) Definitions

As used in this section—

(1) the term "cooperative research and development agreement" means any agreement between one or more Federal laboratories and one or more non-Federal parties under which the Government, through its laboratories, provides personnel, services, facilities, equipment, intellectual property, or other resources with or without reimbursement (but not funds to non-Federal parties) and the non-Federal parties provide funds, personnel, services, facilities, equipment, intellectual property, or other resources toward the conduct of specified research or development efforts which are consistent with the missions of the laboratory; except that such term does not include a procurement contract or cooperative agreement as those terms are used in sections 6303, 6304, and 6305 of title 31;

(2) the term "laboratory" means—

(A) a facility or group of facilities owned, leased, or otherwise used by a Federal agency, a substantial purpose of which is the performance of research, development, or engineering by employees of the Federal Government;

(B) a group of Government-owned, contractor-operated facilities (including a weapon production facility of the Department of Energy) under a common contract, when a substantial purpose of the contract is the performance of research and development, or the production, maintenance, testing, or dismantlement of a nuclear weapon or its components, for the Federal Government; and

(C) a Government-owned, contractor-operated facility (including a weapon production facility of the Department of Energy) that is not under a common contract described in subparagraph (B), and the primary purpose of which is the performance of research and development, or the production, maintenance, testing, or dismantlement of a nuclear weapon or its components, for the Federal Government,

(3) the term "joint work statement" means a proposal prepared for a Federal agency by the director of a Government-owned, contractor-operated laboratory describing the purpose and scope of a proposed cooperative research and development agreement, and assigning rights and responsibilities among the agency, the laboratory, and any other party or parties to the proposed agreement; and

(4) the term "weapon production facility of the Department of Energy" means a facility under th control or jurisdiction of the Secretary of Energy that is operated for national security purposes and is engaged in the production, maintenance, testing, or dismantlement of a nuclear weapon or its components.

United States Health Security National Action Plan:

Strengthening Implementation of the International Health Regulations based on the 2016 Joint External Evaluation

United States Health Security National Action Plan (USHSNAP)

In September 2019, FDA awarded an extramural research contract to conduct a landscape assessment the adoption of advanced manufacturing and identify barriers to adoption within the medical device industry. In September 2020, FDA awarded an extramural research contract to identify barriers to impleme advanced manufacturing in critical production areas such as vaccines and biopharmaceuticals. Such technologies and processes may increase the domestic pr duction of critical MCMs and other medical products needed for pandemic or other response activities.

In FY 2019, FDA signed a Cooperative Research and Development Agreement (CRADA) with the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL).

The CRADA allows FDA to collaborate with biotech stakeholder NIIMBL members, accelerating Agency and industry adoption of biotech innovations.

CRADA

Science and Technology

A Cooperative Research and Development Agreement (CRADA) is a written agreement that facilitates research and development (R&D) collaboration between one or more federal laboratories and one or more non-federal entities. Both parties to a CRADA may provide personnel, facilities, equipment, or other resources, but the government may not provide funding to non-federal entities under a CRADA. CRADAs are authorized by 15 U.S. Code § 3710a. The CRADA fact sheet provides information about DHS CRADAs, when to use a CRADA, who may participate in a CRADA, and the benefits of using a CRADA.

What does a CRADA provide?

- Written agreement between a private company and a government agency
- Collaborative efforts
- Flexible mechanism
- Technology transfer mechanism

What are CRADA's limitations?

- **Rule #1:** Government can provide personnel, services, facilities, equipment, intellectual property, or other resources to the private company's research efforts.
- **Rule #2:** Government can't provide any funding
- **Rule #3:** Private company may provide funds, personnel, services, facilities, equipment, intellectual property, or other resources
- **Rule #4:** Property and equipment will be provided in accordance with established property management policies and procedures.

What is the benefit of CRADA?

- Provide incentives
- Protect any proprietary information
- Allow all parties to the CRADA to keep research results
- Share patents and patent licenses
- Permit one partner to retain exclusive rights to a patent or patent license

Who qualifies for a CRADA?

- Private corporations
- Nonprofit and not-for-profit institutions
- U.S. State and local governments
- Other U.S. federal agencies

Cooperative Research and Development Agreements

Homeland Security
Science and Technology

WHAT IS A CRADA?

A Cooperative Research and Development Agreement (CRADA) is a written agreement that facilitates research and development (R&D) collaboration between one or more federal laboratories and one or more non-federal entities. Both parties to a CRADA may provide personnel, facilities, equipment, or other resources, but the government may not provide funding to non-federal entities under a CRADA. CRADAs are authorized by 15 U.S. Code § 3710a.

DHS CRADAs

CRADAs assist the Department of Homeland Security (DHS) by facilitating collaboration with other entities to leverage the expertise and resources of both parties. The program assists R&D program managers across DHS in establishing CRADAs to support the development and delivery of technology solutions for homeland security end users. The DHS Science and Technology Directorate (S&T) manages CRADAs for the

BENEFITS OF USING A CRADA

CRADAs provide DHS and CRADA partners the opportunity to engage in joint R&D efforts and offer the following benefits:

- Ease of entering into arrangements with DHS to engage in R&D activities
- Access to DHS laboratories' expertise, capabilities, and technologies to foster innovation and improve the economic, environmental, and social well being of the U.S.
- New products, processes, and intellectual property (IP) applicable to DHS mission and commercial goals
- Access to IP resulting from CRADA efforts
- Reduced costs, time, and risk of R&D to achieve DHS mission and/or commercial goals by leveraging external expertise, ideas, investment, and resources
- Joint approaches to solving specific problems by applying different cultural solutions

CRADA ACTIVITIES

WHEN IS A CRADA APPROPRIATE?

CRADAs provide an easy way to collaborate with DHS programs, laboratories, and/or components. CRADAs enable DHS researchers to exchange technical expertise with non-federal partners and protect the rights of both parties to inventions that may result from the collaboration. CRADAs are ideal mechanisms when DHS and an external partner can share resources and expertise not otherwise available to the other party to help advance development of an idea or technology that helps meet homeland security needs.

WHO MAY PARTICIPATE IN CRADAs?

CRADAs must involve at least one non-federal party. In addition to DHS researchers, the other participants in a CRADA may be one or more of the following:

- Private corporations (U.S. or foreign)
- Nonprofit and not-for-profit institutions (U.S. or foreign) including universities and foundations
- State and local governments (U.S.)
- Individuals (U.S. or foreign)

DHS CRADAs support the following collaborative activities that span the R&D lifecycle and increase technology transfer and commercialization readiness: basic research; concept ideation; prototype development; testing and evaluation; technology demonstrations; assessments and pilot deployments; and adaptation of commercial products for government use in DHS mission applications.

CONTACT

If you have questions or would like more information about the DHS CRADA Program, please email CRADA@hq.dhs.gov.